RWANDA STANDARDS

Journal

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TACKLING STANDARDAZISATION IN THE MEDICAL AND PHAMACEUTICAL SECTOR

MEDICAL AND PHARMACEUTICAL TESTING LABORATORY

AN ASSURANCE TO INVESTORS AND CONSUMERS, SAYS RSB DIRECTOR GENERAL

SCOPE OF THE MEDICAL AND

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Rwanda Standards Board
ISO 9001 Certified

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RSB
Rwanda Standards Board
ISO 9001 Certified

RSB CERTIFICATION MARKS

RSB STANDARDISATION MARK

QMS
RSB ISO-9001 REGISTERED

FOOD SAFETY MANAGEMENT
HACCP
CERTIFIED
BY RSB

FOOD SAFETY MANAGEMENT SYSTEM
FSMS
ISO 22000 REGISTERED
BY RSB

EMS
RSB ISO-14001 REGISTERED

TO ALL OUR ESTEEMED READERS

Welcome to this edition of the Standards Journal. The monthly Standards Journal is in line with our commitment to providing standards-based solutions for Consumer Protection and Trade promotion for socio-economic growth in a safe and stable environment.

It focuses on promoting behavioral interventions and promoting adherence to standards within different sectors of the economy, and discussing the pertinent issues on Standards in Rwanda.

The Standards Journal will provide a communication platform between Rwanda Standards Board (RSB) structures, the private sector, investors, consumers and policymakers in form of views, stories, opinions and commentaries on Standardization issues.

It is a platform for Rwandan companies, manufacturers and service providers to showcase their certified products and share their success and educative stories on standardization.

It will navigate our readers through the most pertinent issues on standards, showcase RSB and stakeholder's initiatives, achievements; carry key texts and pictorials on issues to do with standardization in that sector.

In this edition, we bring to you the Pharmaceutical sub-sector in Rwanda. Together with Ministry of Health, the Medical and Pharmaceutical laboratory was launched in December 2017; we are now able to test over 100 drugs commonly used in Rwanda, and we intend to double this number in the next fiscal year. This issue further discusses the role of our esteemed stakeholders; Ministry of Health, Importers of drugs, Hospitals, Pharmacies, National Pharmacy Council, Manufacturers and the public in ensuring standards for medical and pharmaceutical products.

I believe you will find this edition educative, insightful and enriching.

Enjoy reading!

Raymond MURENZI
Director General
Rwanda Standards Board.

MINISTRY OF HEALTH: **ASSURING**

QUALITY OF MEDICINES

Dr. Diane Gashumba, Honorable Minister of Health

The Ministry of Health as the supreme body that monitors all matters relating to health at the national level says it has increased vigilance to ensure high quality of medicines manufactured both in Rwanda and those imported.

The Ministry established specialized branches that monitor drugs from manufacture to consumption.

"The Ministry also uses different mechanisms to ensure that drugs in circulation across the country meet standards for effective treatment of patients," says Malick Kayumba, the Manager of Communication Division in the Ministry of Health.

"When we suspect that a pharmaceutical product was counterfeited, we first quarantine it or recall it from the market. We have Minilabs, a small mobile lab we use to test the molecules. We take samples to be tested at the national medical and phamaceutical testing laboratory for quality assurance. We also send the products for quality testing in accredited and recognized laboratories outside the country in case the drugs to be tested are not in the scope covered by the labaratory in the country," Kayumba adds.

The Government of Rwanda, in December 2017, launched a **hi-tech laboratory facility** to test a wide range of products to ensure quality and safety of regulated products.

"For each batch of product imported, before custom clearance, among the documents requested is the Certificate of Analysis which indicates all tests performed and this is mandatory. If samples require sending them for accredited labs it's also arranged."

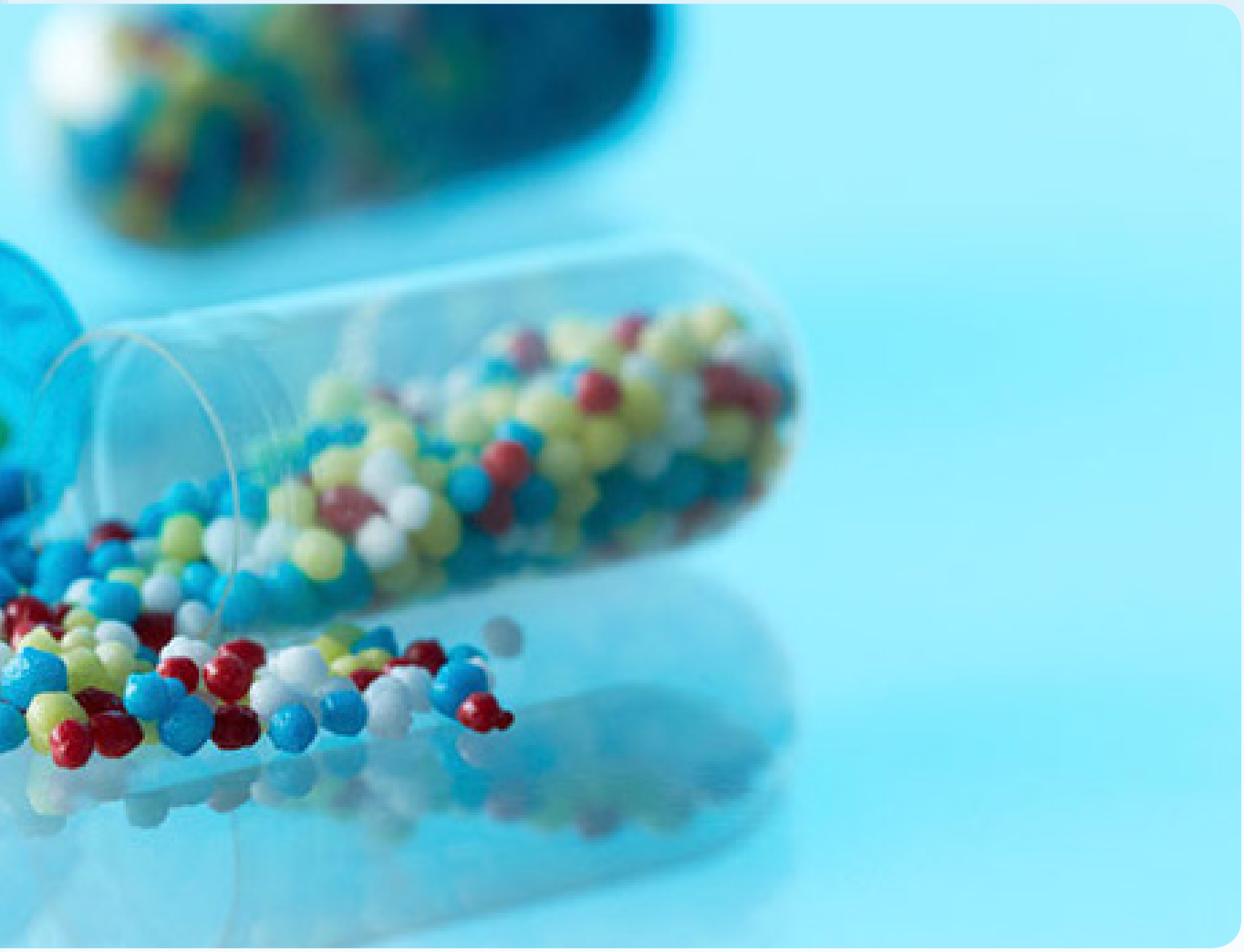
The Government of Rwanda, in December 2017, acquired a hi-tech lab facility to test a wide range of products to ensure quality and safety of regulated products.

The Ministry of Health works with various bodies such as RSB, Medical Products Procurement Division (MPPD), Rwanda Pharmacists Association, Importers of Medicines, ADECOR (Consumers Association) and hospitals to enforce standard, safety and quality, according to Kayumba.

The Ministry regulates all the products imported by MPPD and involves them in the planning and policy document developments for the pharmaceutical sector.

"With the Consumers' Asscociation (ADECOR), we mainly collaborate in development of policy, regulations and guidelines in relation to different medical products regulation for consumer participation and making sure that their views are integrated."

"As regulators, our mandate is to ensure that all pharmaceutical products on the market are of good quality, safe and efficacious, from the manufacturers to the consumers. We therefore, need a strong collaborative mechanism with all stakeholders," says Kayumba.



"We advise manufacturers to respect Good Manufacturing Practices (GMP) to ensure the quality of products released on the market."

Importers, he said, must ensure that the medical products imported are transported, stored and distributed to the dispensers in a manner that will not jeopardize quality.

Kayumba also reminded dispensers to ensure good storage conditions and good distribution practices throughout the whole supply chain.

MEDICAL AND **PHARMACEUTICAL** TESTING LABORATORY

AN ASSURANCE TO INVESTORS AND CONSUMERS, SAYS RSB DIRECTOR GENERAL

Raymond Murenzi, Director General RSB

Last year, Rwanda Standards Board (RSB) launched the medical and pharmaceutical testing laboratory. The laboratory was established in collaboration with Ministry of Health. Our Editorial team caught up with the Director General of RSB, Raymond MURENZI on what Rwandans should expect from the acquired this hi-tech facility. Below are the excerpts.

Qn: Tell us about this laboratory

DG: The medical and pharmaceutical testing laboratory is meant to protect the public health through quality assurance, efficacy and safety of medicinal and related products. The principal function of the laboratory is to analyze medicines for public and private sector to ascertain the level of quality and efficacy of each medicine; imported or locally manufactured, analyze samples for registration and inspection purpose, control of imported medicines and surveying the domestic market (post market surveillance).

The optimal situation is that substandard or counterfeit medicines do not enter the Rwanda market or are identified during production or importation process.

Qn: Does it test every medical drug?

DG: Different drugs and medical equipment are tested for different things. For example, tablets are tested differently from drugs used for injections; each equipment is tested depending on its use and it's done according to the set international standards. Samples are tested to see if they are in accordance with the international standards policy and safe to be consumed by people. A case in point is when testing paracetamol; we carry out qualitative and quantitative tests to ensure that the drug indeed has paracetamol and all other contents in it. This helps to know whether the drug is fit for human consumption or not, or will serve the purpose it is ment for.

Qn: What happens to those drugs found to be substandard?

DG: According to international standards that we follow, every batch is supposed to be tested and this is done through sampling. When a sample is tested and found to be substandard, the whole batch is treated as substandard and disposed of. The whole process is done in line with the International standards manual that consists of rules on standards of medical equipment.

Qn: It must be a hi-tech facility to detect counterfeits

DG: The medical and pharmaceutical laboratory uses high techniques in analysis of pharmaceutical products such as High Performance Liquid Chromatography (HPLC) with Diode Array Detector for screening non-volatile active pharmaceutical ingredients and

organic impurities; Gas Chromatography (GC) for screening of volatile Active Pharmaceutical Ingredients (API); Fourier Transforms Infrared Spectrophotometer (FTIR) and Dissolution apparatus for dissolution test among others.

This laboratory is portioned with each room with different machines. Every machine you have seen in those different rooms has its role in testing. For example, one tests whether the drugs will be effective once used, the other test the acid in drugs; testing whether there was no damage during transportation or whether no damage can arise during transportation locally; whether they will be able to dissolve on the own once swallowed and many other tests. There are also rooms used to prepare drugs to be tested.

Qn: Do you see this laboratory supplementing the national policy of 'Made in Rwanda'?

DG: Rwanda has seen an increased interest of investors especially those expressing interest to invest in the pharmaceutical industry. This laboratory is an assurance to them that their investments will be in safe hands against counterfeits. The legal framework is already in place and we can now ably offer testing services to our investors. This laboratory is one of its kind in the region, it's fully operational and together with the Ministry of Health we have now increased vigilance and collection of various samples from all entry points. RSB has put in place a clear roadmap and a five-year plan for the laboratory. We began by testing 34 mostly used drugs and medicines in Rwanda but today we are able to test 100 different drugs. In the next fiscal year (2018/2019) we intend to increase and double

according to the available budget. The Ministry of Health has got a list of over 1000 drugs and they keep updating the list, our plan is to have all these drugs tested locally in our laboratory.

Rwanda National Police have been active in seizing and arresting those involved in importation and selling of illegal drugs; this laboratory is coming in handy to test even these drugs both for evidence gathering purposes to prove that indeed these drugs are either counterfeits, substandard or harmful to human consumption. It will facilitate scientific investigations for fair justice.

Qn: Do you have a legal framework to punish people involved in selling of illegal, substandard or counterfeit drugs?

DG: The Ministry of Health has put in place a legal framework to curb these criminal acts. There is a law in place; the Ministry has a fully-fledged department that deals with licensing of importers and suppliers of drugs and medical equipment with clear guidelines. At different points of entry, we test all drugs to ensure that these importers have complied with the set guidelines and standards. We give periodical reports on the drugs tested to our counterparts in the Ministry.

Qn: About twelve months down the road now, has this laboratory made any impact?

DG: We have seen a tremendous increase in the quality of drugs being imported. When someone knows that you are able to test and ascertain quality, they are often very careful. Also, in the past we used to send drug samples abroad for testing, this is a thing of the past now. We have seen a reduction in time spent to test drugs and also been able to save money, which we used to spend to have these drugs tested abroad. This laboratory is an assurance to investors that their investment is protected from counterfeits, can easily get tested and checked and to the consumers it is an assurance that they are getting quality drugs.

RSB MEDICAL AND **PHARMACEUTICAL** TESTING LABORATORY

AT YOUR SERVICE

BACKGROUND

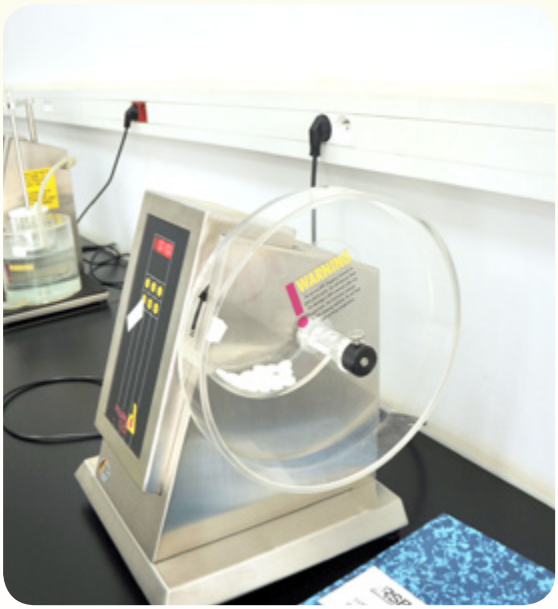
The incidence of counterfeiting pharmaceutical products and the proliferation of substandard quality medicines has been well identified internationally, and constitutes serious health hazards. It is primarily flourishing in developing countries where institutional capacity in testing, inspection and law enforcement is weak and adequate funds for regular drug quality monitoring are missing.

Substandard pharmaceutical products can take all kinds of forms, but the end result is, when administered to a patient that the consequences range from treatment failure, increased toxicity, increased drug resistance, for example, to malaria, Tuberculosis and Acquired Immune-Deficiency Syndrome and even outright death as a result of any of the above.

Owing to the widespread danger of substandard medicines, quality control in the distribution system of developing countries has acquired new dimensions today. If adherence to good pharmaceutical manufacturing, distribution and trading practice cannot be assumed, a greater number of samples have to be tested in order to maintain an appropriate assurance of drug quality.

DEALING WITH THE SITUATION

Rwanda Standards Board has established the Pharmaceutical and Medical Devices Testing Laboratory Unit with the mission to assist the Government of Rwanda to promote and protect public health by assuring the quality, efficacy, and safety of medicinal products and other health commodities.



The principal function of the laboratory is to analyze medicines for public and private sector to ascertain the level of quality and efficacy of each medicine; imported or locally manufactured, analyze samples for registration and inspection purpose; control of imported medicines and surveying the domestic market (post market surveillance). The optimal situation is that substandard or counterfeit medicines do not enter the Rwanda market and are identified either during production or importation process.

The medical and pharmaceutical laboratory uses high techniques in analysis of pharmaceutical products of customer samples such as High Performance Liquid Chromatography (HPLC) with Diode Array Detector for screening non-volatile active pharmaceutical ingredients and organic impurities; Gas Chromatography (GC) for screening of volatile active pharmaceutical ingredients (API); Fourier Transforms Infrared Spectrophotometer (FTIR) and Dissolution apparatus for dissolution test among others.

SCOPE OF RSB PHARMACEUTICAL LABORATORIES

Medical and Pharmaceutical Testing laboratory currently produce reliable and accurate results in pharmaceutical area of the following parameters in Capsules and Tablets of anti Malaria, antiretroviral, Anti tuberculosis.

- **Assay on the active ingredients and Purity (Chromatography, Titration, Limit Tests)**
- **Identity of product (Spectroscopy, Chromatograph),**
- **Water content (loss on drying, Karl Fisher Titration),**
- **Appearance and friability**
- **Uniformity of mass/dosage units**
- **Disintegration and dissolution studies**
- **Particle size analysis**
- **Acidity and alkalinity of solution**

Medical devices are also tested such as female condoms, male condoms and medical gloves. The laboratory is planning in the near future to start testing for microbial limits tests, sterility testing, microbial contaminant identification, preservatives testing and microbial challenges, bacterial endotoxin and studies of extractable and leachable etc..

SCOPE FOR MEDICAL AND PHARMACEUTICAL TESTING LABORATORIES

EM: Essential Medicines
NEM: Non Essential Medicines
NU: Not in Use but for investigation purpose

	THERAPEUTIC CLASS + NAME OF MEDICINE	Classification (EM, NEM,NU)
S/N	ANTIMALARIA MEDICINES	
1	Artesunate powder for injection	E M
2	Arthemeter /Lumefantrine(coartem) tablet	E M
3	Quinine tablet	E M
4	Mefloquine tablet	E M
5	Amodiaquine hydrochloride tablet	NU
S/N	ANTIBACTERIAL AND ANTIPROZOAL MEDICINES	
1	Amoxicillin capsules and tablet	EM
2	Ampicillin powder for injection	EM
3	Cefixime tablet	EM
4	Nalidixic acid	EM
5	Cefalexin	EM
6	Azithromycine tablet	E M
7	Chloramphenicol capsule	E M
8	Tetracycline tablet	E M
9	Cefuroxime tablet	NEM
10	Ciprofloxacin tablet	E M
11	sulfadoxine/Pyrimethamine	NU
12	Cloxacillin capsule	EM
13	Sulfamethoxazole/Trimethoprim tablet	EM
14	Ofloxacine tablet	EM
15	Norfloxacine tablet	EM
16	Nitrofurantoine tablet	EM
17	Moxifloxacine tablet	E M
18	Levofloxacine tablet	E M
19	Clarithromycin tablet	E M
20	Erythromycine tablet	E M
21	Doxycycline hyclate capsule	E M
22	Metronidazole tablet	E M
23	Amoxicillin &Clavulanic acid tablet	EM

	THERAPEUTIC CLASS + NAME OF MEDICINE	Classification (EM, NEM,NU)
S/N	ANTIBACTERIRAL FOR TUBERCULOSIS(ANTITUBERCULOSIS) MEDICINES(single or Fixed dose combination)	
1	Isoniazid tablet	E M
2	Rifampicin tablet	E M
3	Ethambutol tablet	E M
4	Pyrazinamide tablet	E M
5	Kanamycinesulfate	E M
6	Streptomycine for inj	E M
S/N	ANTIFUNGAL MEDICINES	
1	Nystatin tablet	E M
2	Fluconazole tablet	E M
3	Griseofulvin tablet	E M
4	Ketoconazole	E M
S/N	ANTHELMINTIC MEDICINES	
1	Tinidazole tablet	EM
2	ALBENDAZOLE tablet	EM
3	Mebendazole tablet	EM
4	Praziquantel tablet	EM
S/N	ANTIALLERGIC MEDICINES	
1	Chlorpheniramine maleate tablet	EM
2	Promethazine hydrochloride tablet	EM
3	Salbutamol tablet	EM
4	Aminophylline tablet	EM
S/N	ANTIPSYCHOTICS-ANTIDEPRESSANT-ANTIEPILEPTIC MEDICINES	
1	Carbamazepine	EM
2	Amitryptiline hydrochloride	EM
3	Haloperidol tablet	EM
4	Phenytoine tablet	EM
5	Valproic acid capsule	EM
6	Chlorpromazine tablet	EM

	THERAPEUTIC CLASS + NAME OF MEDICINE	Classification (EM, NEM,NU)
S/N	MEDICINES ACTING ON GASTROIN-TESTINAL TRACT(antidiarrheal,AN-TIVOMITING,LAXATIVES MEDICINES)	
1	Bisacodyl tablet	EM
2	Metoclopramide tablet	EM
3	Loperamide Hydrochloride tablet	EM
S/N	VITAMINS AND SUPPLEMENTS	
1	Thiamine hydrochloride tablet	EM
2	Ascorbic acid tablet	EM
3	Folic acid tablet	EM
4	Pyridoxine tablet	EM
5	Riboflavine(Vit B2)	NEM
S/N	ANTINFLAMATORY-ANALYGESIC-ANTIPYRETIC MEDICINES	
1	Acetylsalicylic acid tablet	EM
2	Ibuprofen tablet	EM
3	Tramadol hydrochloride tablet and capsule	EM
4	Diclofenac sodium tablet	EM
5	Prednisolone tablet	EM
6	Indomethacin tablet and capsule	EM
7	Paracetamol tablet	EM
8	Codeine Phosphate	EM
S/N	ANTIHYPERTENSIVE MEDICINES	
1	Furosemide tablet	EM
2	Amlodipine besilate	EM
3	Losartan potassium tablet	EM
4	Hydrochlorothiazide tablet	EM
5	Bisoprolor fumarate tab	NEM
6	Atenolol tablet	EM
7	hydralazine tablet	EM
8	Propranolol hydrochloride tablet	EM
9	Nifedipine tablet	EM
10	Captopril	EM

S/N	ANTIACID AND ANTIULCERS MEDICINES	
1	Omeprazole capsules	EM
2	Ranitidine hydrochloride tablet	EM
3	Cimetidine tablet	EM
	ANTIRETROVIRAL MEDICINES(Single	
1	Lamivudine tablet	EM
2	Zidovudine tablet	EM
3	Nevirapine tablet	EM
4	AbacavirSulfate	EM
5	Effavirenz tab	EM
6	Tenofovir	EM
	ANTIDIABETIC	
1	Glibenclamide tablet	EM
2	Metformine hydrochloride tablet	EM
	OTHERS	
1	Clomifene citrate tablet	EM
2	Acetazolamide tablet	EM
3	Warfarine for inj	EM
4	Progesterone tab	EM
5	Cycloserine tab	EM
6	Oxytocin for inj	EM
7	Acyclovir tab	EM
8	Allopurinol tab	EM
9	Levothyroxine tab	EM
10	Neostigmine bromide for injection	EM

LIST OF PARAMETERS THAT CAN BE TESTED CURRENTLY

Parameters for Tablets	Parameters for Capsules	Parameters for Powder for Injection
1.Identification	1.Identification	1.Identification
2.Assay	2.Assay	2.Assay
3.Friability test	3. Disintegration test	3. Uniformity of weight
4.Disintegration test	4. Uniformity of weight	4.pH
5.Uniformity of weight	5. Dissolution	
6.Dissolution	6. pH	
7.pH		

TRAINING OF ADECOR MEMBER ON STANDARDIZATION

OF MEDICAL AND PHARMACEUTICAL PRODUCTS

It is part of the mandate of RSB to develop and publish national standards, disseminate information on standards and organize training programs for its stakeholders in the area of standardization.

To continue to fulfill its mandate, the standards body, has held workshops with members of Association pour la Defence des Droits des Consommateurs au Rwanda (ADECOR) on standardization.

ADECOR is an Association aiming at disseminating consumers' rights and helping them to defend their rights.

The workshop held in Kigali was attended by 25 ADECOR members. They were trained on

ADECOR is represented in all provinces, and has more than **350 volunteer** members across the country.

the standards of medical and pharmaceutical products, and other substandard consumables that may put the lives of consumers at stake.

The Director General of RSB, Raymond Murenzi, while addressing participants reminded them that consumers are the ones that are affected by lack of standards, and "must play an important role in fighting for their rights."

"150 people can not take care of lives of 12 million people, it is not the task of RSB or the government alone; consumers should intervene, be actively part of the standardization process and claim their rights to have quality and standard medical and products and services," Murenzi emphasized.

According to the RSB Director of Standards Education, Research, Information and Documentation Unit, Liliane Kamanzi, RSB develops standards and trains stakeholders on them. She calls upon those trained to apply these standards to the highest levels as required.

The Executive Secretary of ADECOR NDIZEYE Damien lauded the role of RSB in educating consumers.

"Such training is very important in raising awareness and educating people on the standards of medical and pharmaceuticals. This should be continuous as we work together for the wellbeing of Rwandans" Ndizeye said.

One of the participants, Fraterne Manishimwe expressed his happiness for being part of the training.

"I have understood my rights as a consumer but also my role as an implementer. There are things we tend to ignore or even don't know like checking if the products we are buying are not expired or if they bear the S-Mark—Standard Mark," Manishimwe said.

About ADECOR

It was legally established in 2008 as Non-profits Organization. Loosely translated in English as Rwanda Consumers' Rights Protection Organization, ADECOR is also registered by Rwanda Governance Board (RGB) under the new Law no 04/2012 of 17/02/2012 governing the organization and the functioning of National Non-Governmental Organizations.

The establishment of ADECOR was based on four fundamental rights of consumers:

Right to a decent life (safe and quality goods and services);

Right to free choice (accessibility to multiple and affordable choices of goods and services),

Right to information (about prices and descriptions and effects of products and services), and finally

Right to be heard (being able to express his/her satisfaction or grievances and get appropriate remedies).

ADECOR is represented in all provinces, and has more than 350 volunteer members across the country.

Working closely with other Civil Society Organizations, Private sector Actors and Government institutions, ADECOR is increasingly building a Consumer Voice in Rwanda.

As an affiliate member of Consumer International (CI), ADECOR enjoys good working relations with regional and global consumer organizations.

Its mandate includes ensuring that all medical and pharmaceutical products consumed by the people comply with the international set standards, owing to the fact that consumers are the engines of the country's economic growth.

DRUG QUALITY ASSURANCE

AND ACCREDITATION OF HOSPITALS

Assuring standards and quality of medical drugs is one of RSB's efforts to ensure patients recover well from sickness; to be certain that each medicine reaching a patient is safe, effective, and of standard quality. The role of medical facilities like hospitals and clinics in quality assurance, therefore, can't be undermined.

Quality Assurance activities in a hospital or clinic should be comprehensive, spanning the entire supply process from medicine selection to patient use. The whole supply chain from manufacturing process, packaging, transport, supplying, storage and consumption or use in medical facilities should guarantee quality gains, credibility and safety.

Public hospitals acquire medicines for patients through the supply chain set by Ministry of Health, which directs the Medical Procurement and Production Division to import and distribute medical drugs in district pharmacies, which also supply hospitals.

The Standards Journal spoke to the management in some of the public and private hospitals on how Quality Assurance is guaranteed in their facilities, to meet accreditation requirements.

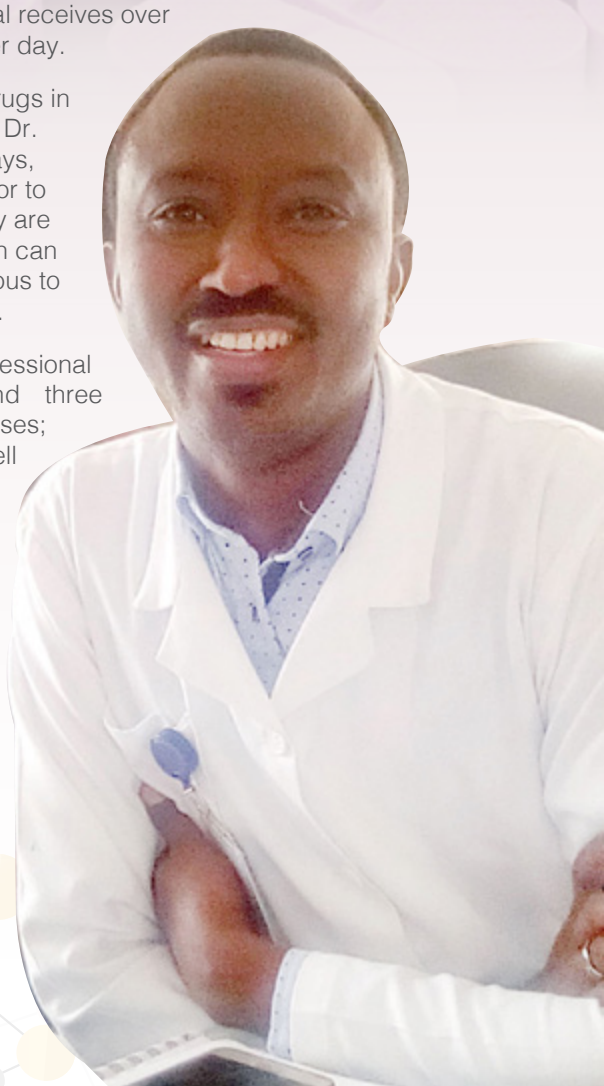
"There are rare cases where a certain drug is out of store in district pharmacies, they give us no-objection to buy them from accredited private pharmaceutical companies," says Dr. William Rutagengwa, the Director General of Muhima Hospital.

"These private dealers are licensed, the government has institutions that monitor them to ensure compliance with the set standard guidelines through different control mechanisms along the supply chain, which also assures us that what we are buying from them is of the required quality and standards," Dr. Rutagengwa adds.

Muhima hospital receives over 200 patients per day.

The safety of drugs in hospital stores, Dr. Rutagengwa says, is a critical factor to ensure that they are not spoilt, which can also be disastrous to patients' health.

"We have a professional pharmacist and three pharmacist nurses; they are well trained on



Dr. William Rutagengwa, Director General of Muhima Hospital

Dr. Pierre Célestin Kanimba, proprietor of Polyclinique la Medicale

pharmacy management. They manage the hospital medicine stores and ensure that medical consumables and equipment maintain the quality and safety of patients," explains Dr. Rutagengwa.

ON PATH TO ACCREDITATION

"We are on the right path to get the hospital certified. We are at Level One, although to be accredited requires three levels," he noted. Certification shows us standards, policies and procedures of every activity including how to manage medicine storage rooms conditions; requirements for the medicines storing room; condition of other equipment such as fridges; what types of drugs to be put on shelves and at what height from the ground

We are on the right path to get the **hospital certified**. We are at Level One, although to be accredited requires three levels

level; level of temperature, amount of incoming air among many other internationally accepted standards required for the storage, which we try to comply with," Dr. Rutagengwa explains.

"The certification process looks at all things including management of medicines, how we treat patients, how to manage equipment such as machines, sterilization, waste disposal and many others because there are about 75 standards within the three levels, required for accreditation," he adds.

DEALING WITH EXPIRED DRUGS IN HOSPITALS

According to Dr. Rutagengwa, the hospital currently uses Electronic Logistics Management System (ELMS) in buying drugs from district and private licensed pharmacies.

"ELMS help us to know what drugs we have in stores and the chronological arrival of drugs, which enables us to detect those that are about to expire or those that have expired by using first-in first-out (FIFO) method. We also check the drugs before buying them to avoid those that are substandard and expired."

He explains that they also project most drugs needed and used to avoid expiration.

"If any medicine expires we send a report to the Ministry of Health. This is because there is a ministerial order on waste disposal to avoid air pollution and contaminating the environment in general."

Equally, Dr. Pierre Célestin Kanimba, the proprietor of Polyclinique la Medicale says they order few medicaments as it has been recommended by the Ministry of Health. The guidelines don't allow polyclinics to have a pharmacy.

"There is need for discussion with the ministry to study again on how to allow us to also have a pharmacy and pharmacists to assure the safety and standard of medications," says Dr. Kanimba.

Currently, Dr. Kanimba says they buy few drugs to avoid spoilage and expiration.

"Some are stored in fridges, others in required normal temperature, away from sunlight and much coldness to prevent spoilage," he explained.

He also said that they trust quality and standards of the drugs they purchase considering that they are acquired from licensed dealers that are also regularly inspected.

MPPD: AN OPEN EYE FOR STANDARDS

Immaculée Mukankubito, Quality Assurance Professional at MPPD

The Medical Procurement and Production Division (MPPD), operates under Rwanda Biomedical Centre (RBC). It is a national importer and drug storing center formerly known as CAMERWA that ensures that quality and cost effective drugs and medical equipment are available to the population.

It ensures equitable access of quality cost effective drugs and medical equipment, and procures world class quality pharmaceutical products, storage standards and distribution of medical commodities through a computerized management system.

Immaculée Mukankubito, a pharmacist from Quality Assurance Unit at MPPD, explained that

> RSB helps us to set standards, right from **MAGERWA.** The samples that they test informs us on our next step

effective and standard storing ensures quality and safety for human consumption.

She says in collaboration with RSB drugs are first cross-checked to ensure they meet international standards at all points of entry into the country and before being accepted into MPPD storing center.

“The verification is done jointly with Rwanda Standard Board (RSB) to scientifically assess if the drugs meet all required standards, if they were not affected in any way during transportation, and that’s when we say, this consignment can be taken to the warehouse.” says Mukankubito.

“RSB helps us to set standards, right from MAGERWA. The samples that they test inform us on our next step. In case of a query, the affected medicine is put in quarantine and only released when approved by the Ministry of Health.”

MPPD has three major storing levels of temperatures; the under-cold room with freezer of between 2 and 8°C to ensure drugs stay with their original quality; the room temperature with normal heat that does not go above 30°C; and controlled room with 25°C.

“These storing conditions are checked on a daily basis; thermometers are caribrated and installed in different angles of the stores to record temperatures. Maintenance and hygiene are also essential but we also work with RSB, which assists us in calibration to check if the systems still operate well,” Mukankubito explains.

At least 70% of the imported medical drugs pass through MPPD for quality control and 30% by private importers. Manufacturers and suppliers are those approved by the World Health Organization (WHO), according to Mukankubito.

"We do this to ensure we buy from a trusted supplier, but we also go an extra mile to conduct tests in other internationally recognized laboratories."

NATIONAL PHARMACY COUNCIL: THE VOICE OF PHARMACY PROFESSION

Dr. Raymond Muganga, Chairperson of National Pharmacy Council

In a bid to accelerate medicines' quality assurance and customer care service delivery, the National Pharmacy Council (RPC) affirms that various efforts have been put in place to regulate pharmacy professionals in order to promote good practices.

The NPC was established by the law No 45/2012 of 14/01/2013 with the aim to regulate and control pharmacy profession.

Since its inception in 2014, the council has established various initiatives to make the sector more beneficial to the people they serve, and avoid any kind of malpractices that can cause health risks to drugs consumers.

The efforts complement that of Rwanda Standard Board (RSB) to ensure that all imported drugs are tested to guarantee standards and quality. Thus, the Council also goes further to inspect pharmacies and professional pharmacists to ensure they comply with set standards, and fighting or preventing sale of counterfeit products.

According to Dr. Raymond Muganga, the Chairperson of NPC, they advise pharmacists to keep purchasing medicines from licensed medicines importers.

"When purchasing medicines we advise them to work with suppliers who are licensed and trusted. We warn them that drugs that enter their

pharmacies through illegal manner is a crime and punishable by the law. We advise them to work in compliance with laws and guidelines on quality assurance of medicines," said Dr. Muganga.

Darius Uzabakiriho, the Permanent Secretary of the Council, adds: "We regulate pharmacy professionals and advise University teaching pharmacy programmes by giving them professional measures to avoid malpractices."

In case of malpractice amongst pharmacy professionals, Uzabakiriho says, the Council suspends those implicated, and suspends a pharmacy that does not follow or comply with the standards.

"We work hand-in-hand with the Ministry of Health to ensure all good practices are met to preserve drugs' safety for quality assurance," says Uzabakiriho.

Quality of medicine will be maintained in such coordinated manner to **detect and eliminate** counterfeit drugs

Darius Uzabakiriho, Permanent Secretary National Pharmacy Council

Malpractices, according to Uzabakiriho, include illegal pharmaceutical products in the pharmacy, giving wrong and expired drugs to the patient or poor descriptions; although he maintains that such cases are rare.

"It would be something unusual for professional pharmacist to give wrong drugs to patients; rather it can be a medication error. We continue to equip Universities with updated professional teaching programmes to avoid such," he said.

The Council has put in place professionals' Code of Conduct and relevant judgments on practices to protect the population, who consume medicines.

"We conduct research and knowledge gap analysis to ensure that our professionals work more professionally, and take disciplinary measures, where need be. A pharmacy should be registered and having a legal license; should have an effective system to trace medicines and those expired."

The Council, Uzabakiriho says, works with RSB in ensuring safety of drugs, track fraudulent drugs in pharmacies and to see if they acquire drugs from licensed importers.

"Quality of medicine will be maintained in such coordinated manner to detect and eliminate counterfeit drugs," he notes.

There are over 800 registered pharmacies across the country, but the Council says these are still few compared to the market demand.

At least 15 cases of distribution of poor quality pharmaceutical products, and 56 illegal and substandard pharmacies that were opened without a pharmacist staff were recorded between 2015 and 2017. Six individuals were last year punished for the anomalies registered in the same period.

An assessment by the Council also reveals that there are some pharmaceutical products that are smuggled into the country, which raises concern of quality and standard.

Pharmacies are advised to comply with ethical standards, report illegal dealers and the public to buy from recognized pharmacies to avoid buying counterfeits, which are harmful to their health.

SAFETY OF DRUGS AND MANAGEMENT OF

EXPIRED DRUGS IN PHARMACIES

Pharmaceuticals' value chain is a very critical way that requires much attention to sustain quality and health of consumers or patients. The chain has to be traced from manufacturers, to the pharmacist, who deliver or sells medicines to patients.

Virgile Iyakare, a pharmacist working in one of the private pharmacies in Kigali, said they also purchase pharmaceutical products from licensed wholesalers.

"We follow all safety and standard guidelines set-forth by Rwanda Standards Board including how wholesalers store them to maintain quality of drugs," said Iyakare.

"Drugs can be affected or spoilt during transportation and storage. The storage condition can spoil the drugs and it's a critical factor we consider when buying. It is a policy that our professional pharmacists also have to check every medical consignment that we bring in to ensure that what we have in store fulfills all the standards," he explained.

The pharmacist said that the lack of quality sometimes is observed on packaging, where some packs are missing in particular drug boxes.

Virgile Iyakare, Pharmacist

Normally when we encounter such cases, **we take the affected drugs back** to the wholesaler… we don't take any risk

"If a set or pieces are missing in a box, it provides space for the drugs to shake, which might cause friability. If all pieces are packed well in the box, it keeps it intact during transportation," Iyakare observed.

"Normally when we encounter such cases, we take the affected drugs back to the wholesaler… we don't take any risk."

He, however, emphasizes daily control and hygiene, and temperature of drug stores. "This should be done in the morning, afternoon and evening," he says, "to prevent any spoilage that may arise out of unfavorable temperature and hygiene."

"Drugs are kept in different conditions. Some can need temperature that varies between 2 and 8 degrees Celsius, others require 25°C. We

have thermometer that usually measures the temperature to ensure drugs are in the required conditions."

Dealing with expiration

Iyakare explains that they set up 'Ishyiga Technology' to control expiration of medicines.

"These drugs are recorded whenever they are brought in, and the system immediately marks date, quantity of drugs and storing conditions whereby the drug nearing to expire is easily detected," he says.

"We do store review on monthly basis to select drugs that are approaching expiration date by using the FFO (First expired, first out) system. We notify the Ministry of Health which helps in environmentally friendly waste disposal, and Rwanda Revenue Authority (RRA) to help us calculate losses. This is about accountability and protection of the ecosystem," he says.

"We deal with people's health, and that calls for maximum standard and quality, continuous operations against counterfeit or substandard pharmaceutical products."

WHOLESALE DRUG DISTRIBUTION: **PROTECTING THE INTEGRITY OF**

THE NATION'S PRESCRIPTION DRUG SUPPLY

It is often a good practice for pharmaceutical importers to double-check their products to be more certain that the health and standard guidelines are respected so as not to expose consumers at risks that might arise out of substandard or fake drugs.

Eric Gashabuka of Phillips Pharmaceuticals Rwanda Limited, one of the accredited importers, says dealing in pharmaceutical business requires 'scientific vigilance' and following every guideline because 'you are dealing with the lives of people.'

"Any error or malpractice you make when dealing in pharmaceutical business count it as lives killed," says Gashabuka.

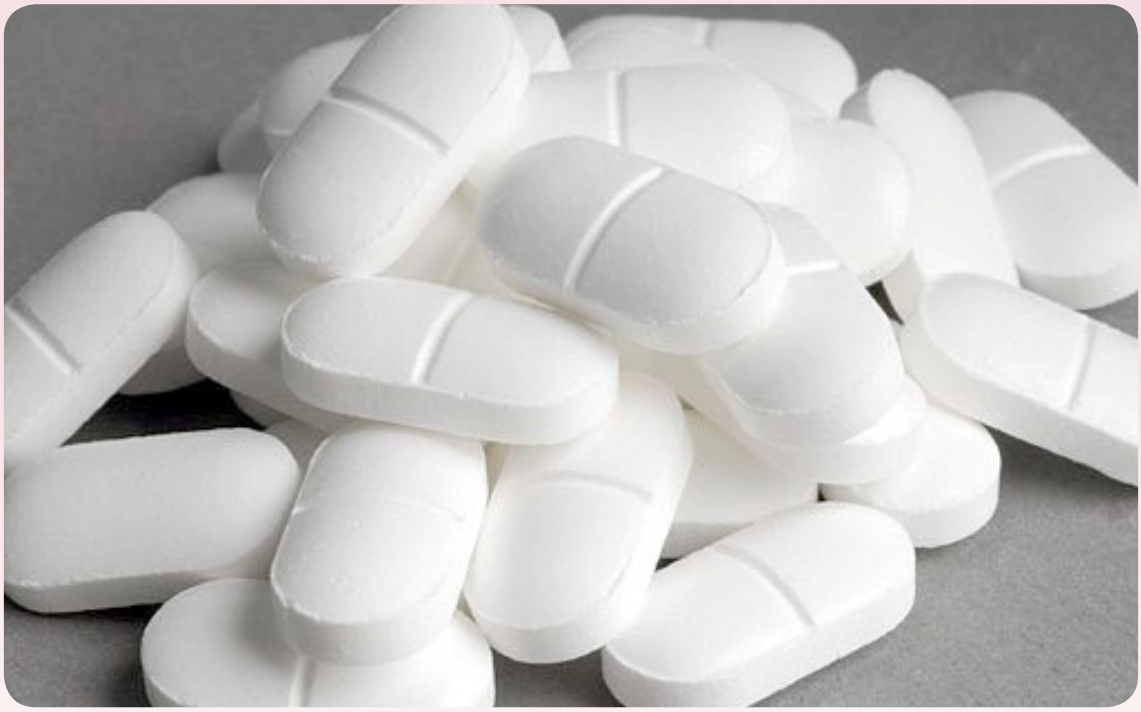
Phillips Pharmaceuticals Rwanda Limited has been in the drugs business for at least 12 years.

"You have to be registered and licensed by the Ministry of Health, and get a market registration order for the medicines before you start importing. Invoices, packing list certificate of analysis and license and following the ministry's process of importation are all important factors to ensure quality and standard of the drugs," he adds.

It is a norm that Rwanda Standards Board has to check all drugs imported before they are cleared in the national warehouse—MAGERWA.

Gashabuka emphasizes that the medicine should have batch numbers.

Batch number is a reference number - it is an internal number private to manufacturer, to access & check should there be any contamination issues which may also include some information on raw material contamination, potency test records, and process control data, among others.



TRANSPORTATION

"We have quality agreements with manufacturers. Good Distribution Practices (GDPs) that include humidity, cooler box and temperature to avoid damages during transportation have to be respected," says Gashabuka.

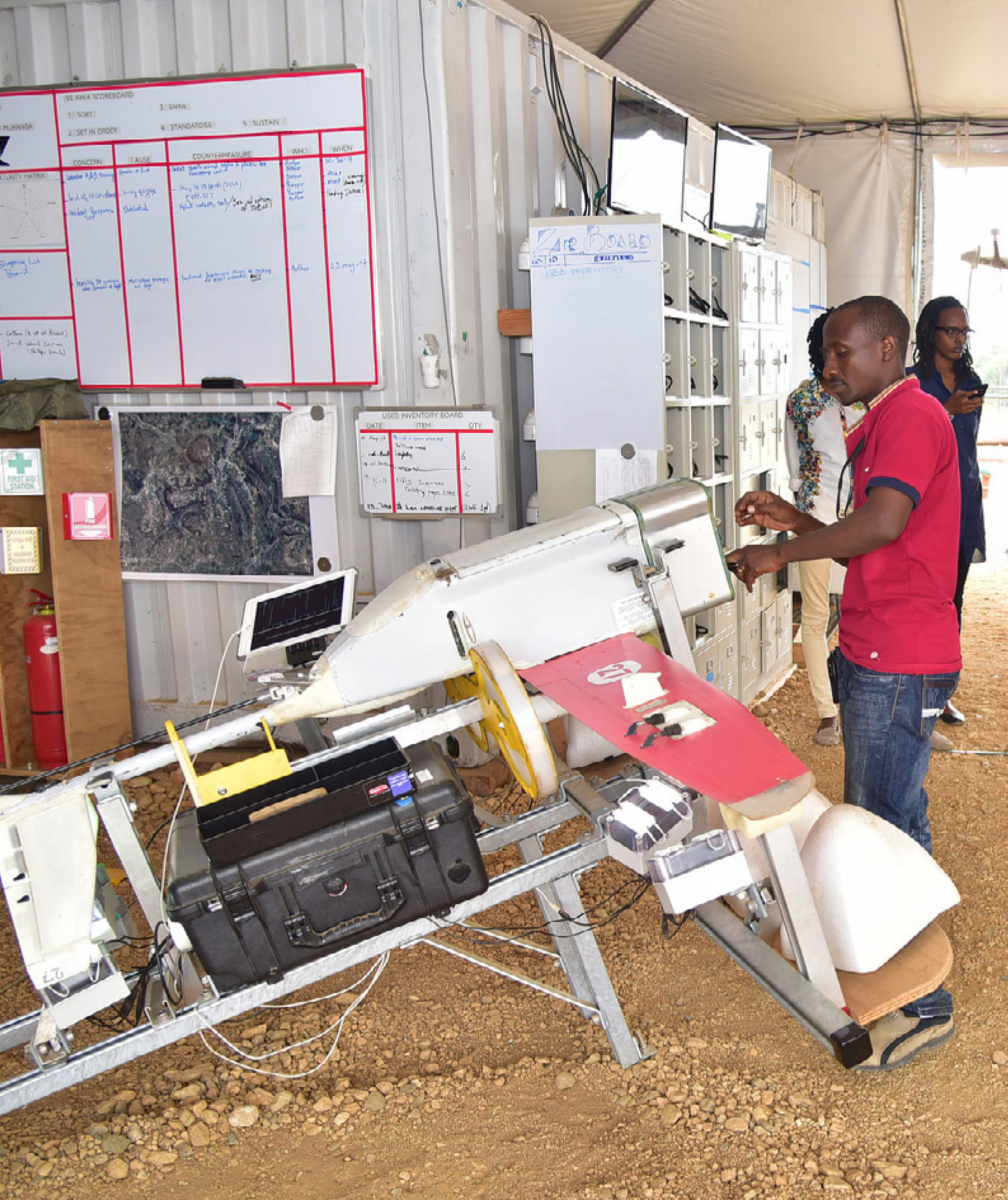
Freezers and cooler boxes with icepacks are some of those used to keep drugs safe in their normal humidity conditions.

Expired medicines are put in quarantine and reported to be disposed of in an environmental friendly way, according to Gashabuka.

"We work with RSB and the Ministry of Health to ensure that everything is done in the right way. The Ministry has also eased the importation process, with the importation license application now done online. We also get training on drug management. All these help us to be perfect in what we do."

Jean Pierre Nkeziyaremye of AFRI PHARM, another licensed wholesaler says purchasing from recognized manufacturers also guarantees quality.

"Even those transporting the drugs are given guidelines; one is that drugs should be intact… should be transported in such a way that they will not break," says Nkeziyaremye.


USED INVENTORY BOARD
DATE
ITEM
QTY
FIRST AID STATION

MADE IN RWANDA MEDICAL CONSUMABLES AND LABORATORY PRODUCTS NOW AVAILABLE!

PHARMALAB ENSURES HIGH QUALITY TO MEET INTERNATIONAL STANDARDS

Cecile Nkomeje, PharmaLab Ltd Managing Director

PharmaLab Limited provides a range of medical consumables and laboratory products that meet market demands with high quality at competitive prices and an absolute orientation towards service.

For Quality assurance, PharmaLab is ISO certified, meaning its products and services meet international standards including ISO 9001:2015, ISO 14644-1, EN1420:2004 and ISO6710:1995

To ensure quality production process for products, they use ISO 6710:1995 and ISO 14644-1.

Observation of standards begins with using quality raw materials which are separately kept and tested before they are released for use in the production process.

During the production process, raw materials pass through different phases of treatment in

For Quality assurance, PharmaLab is **ISO 9001 certified,** meaning its products and services meet international standards

the clean-room to avoid any external contact that would otherwise breed contamination. In the clean-room, everything entering, including the air is purified and sterilized.

The plant manufactures seven types of tubes; six of them having two years of shelf-life while one lasts one year and half.

The company also conducts two internal forensic audits in a year and regular external audits by consultants, regulatory bodies like Rwanda Standards Board and Rwanda Biomedical Center as well as the Ministry of Health to ensure the quality of their products.

OUR PRODUCTS

PharmaLab produces three types of products; Vacuum Blood Collection Tubes, Urine Collection Containers and Stool Collection Containers.

VACUUM BLOOD COLLECTION TUBES

PharmaLab VacuTubes are plastic tubes (medical grade polyethylene terephtalate—PET). The cap in polyethylene is assembled with rubber stopper in chlorobutyl.

Except for the no additive tubes, all other types contain additives which are intended to preserve blood ingredients (glucose), facilitate or inhibit blood coagulation and allow obtaining the desired type of sample (serum, plasma or wall blood).

Each tube includes a paper label with different information related to the manufacturer, product identification, expiration date and storage conditions. A vacuum is created in tube to regulate the draw volume sample blood.

URINE COLLECTION CONTAINERS

This is made with polypropylene (PP M00E) and colored screw cap in polypropylene: PP T300, 30 ml of volume and packaging 500 packs.

Stool Collection Containers

This made with polypropylene (PP A 180TM) with colored screw cap (in polypropylene: PP T300), 30 ml of volume and packaging 500 pcs.

When measuring the constituents of products especially for Blood Collection Tubes, they consider five parameters which are concentration, vacuum, physical appearance, friend matter and sterility.

The plant hasn't encountered any problem related to the quality of their products as the Quality Assurance Unit articulately follows standard to avoid any product that would go on the market without meeting standards requirement.

ON THE MARKET

According to Cecile Nkomeje, the PharmaLab Ltd Managing Director, their products are well received on local and international market.

She says, in a recent visit by the Ministry of Trade and Industry in Tanzania with the Rwandan business community, their products were showcased and they received high recognition.

"They were curious to observe that Rwanda could produce such good products and they decided to visit us to witness the production process. They liked our products and we signed a memorandum to represent our products in Tanzania," she explains.

PharmaLab's products also won a market in Uganda, and have also penetrated the market in the DR. Congo.

ON EXPANSION

"This gives us hope that after succeeding on the Rwandan market and good expansion to regional markets, we will start making new products of medical and laboratory consumables," Nkomeje says.

ABOUT PHARMALAB

PharmaLab Ltd is an exclusive distributor in Rwanda of a Germany company Human Diagnostics GMBH and a Manufacturing Company of medical and laboratory consumables.

As of today, it is the leading company in Rwanda in the vitro diagnostics with a broad range of products from the smallest to the biggest products including Laboratory Analyzers systems and the full range of reagents for Chemistry, ELISA, Haematology, Haemostasis and rapid testing diagnostics.

They are specialists in the manufacture of a range of products including all types of blood tubes collections, stool containers and urine containers for the first time and then a large game of medical consumables.

There are Specialists in Selling Medical Equipments, Laboratory Reagents and Medical consumables products supplies. PharmaLab Ltd has a full-fledged service and maintenance managed by well trained Engineers/ Technicians.

STAY HEALTHY; BUY PRESCRIBED DRUGS

FROM RECOGNIZED PHARMACIES

It is recommended that you consume drugs that are prescribed and meet quality standards. Some people are so observant while others are not. Manufacture and expiry dates are important features to observe when purchasing on before consuming or using drugs. You equally own your life.

Remy Kinani, a resident of Ntarama sector in Bugesera District, says: "When it comes to getting drugs from the pharmacist or any other individual involved in the distribution of drugs you have to differentiate between business and healthcare."

According to Kinani, "Any person seeking medication must verify that the medicine acquired has not exceeded the expiry date, check if its container bears the mark of the manufacturer."

He advises against buying medication from unrecognized sellers, calling it "Putting your life at risk."

Like Kinani, **Hyacinthe Umurungi**, a social worker from Gatenga in Kicukiro District, castigates the acquisition of drugs without prescriptions or not following prescriptions by a medical expert.

She advises that "It is healthy for us to consult medical experts when we are sick to find out which medicine we need and how to use it."

According to Umurungi, pharmacies shouldn't sell drugs to people without prescriptions by a medical expert.

To pharmacists, she recommends informing patients about the standards of the medicines they sell to them, particularly with regard to their expiration date, especially for medicines that are usually kept at home for a long time waiting for a possible crisis, such as painkillers, antibiotics or anti-inflammatory.

Equally, **Sam Byaruhanga**, "Getting drugs on the street or from unrecognized vendors is a health risk because there is nothing to reassure you about their quality or compliance with standards."

"Some commonly used pharmaceuticals such as those that cure headaches, people just buy them without prescription… it has become like a usual thing but dangerous," says Byaruhanga.

Without condemning the fact of having "A small family pharmacy", Byaruhanga advises that those who do so to be mindful of the expiry date, preservation and storage conditions, and keeping them out of reach of children.

STANDARDS FOR

PHARMACEUTICAL PRODUCTS

✓	RS 74-1: 2017	Quality assurance of pharmaceuticals — Good manufacturing practices and inspection — Part1: Main principles for pharmaceutical products
✓	RS 74-2: 2017	Quality assurance of pharmaceuticals — Good manufacturing practices and inspection — Part 2: Starting materials
✓	RS 74-3: 2017	Quality assurance of pharmaceuticals — Good manufacturing practices and inspection — Part 3: Specific pharmaceutical products
✓	RS 74-4: 2017	Quality assurance of pharmaceuticals — Good manufacturing practices and inspection — Part 4: Inspection
✓	RS 91: 2015	Labeling and marking of pharmaceutical products — Specification
✓	RS 337-1: 2017	Mosquito repellents — Specification — Part 1: Mats containing allethrin
✓	RS 337-2: 2017	Mosquito repellents — Specification — Part 2: Coils containing allethrin

STANDARDIZATION

OF TRADITIONAL MEDICINE

Kampeta Sayinzoga, Director General NIRDA

Traditional medicine is the backbone of the pharmaceutical industry. Also known as indigenous or folk medicine, traditional medicine comprises medical aspects of traditional knowledge that developed over generations within various societies before the era of modern medicine.

The World Health Organization (WHO) defines traditional medicine as "the total sum of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness."

In developed countries, herbal medicines came into limelight largely due to the advancement in Research and Development.

In Rwanda, several traditional medicines manufactured and commercialized on local markets, however, still face production standard challenges, although experts say this issue is being addressed.

According to Dr. George Nyombaire, Head of Research and Development Coordination Department at the National Industrial Research and Development Agency (NIRDA), validation of efficacy, regulation of safety, standardization of materials and process, lack of innovations and reference compounds for quality control of these traditional medicines are some of the challenges at hand.

Dr. George Nyombaire, Head of Research and Development Coordination NIRDA

"Consequently, the quality of traditional medicines needs to be improved through research for the safety of consumers," says Dr. Nyombaire.

He adds: "Traditional medicines should, therefore, not be regarded as a static body of unchanging knowledge, but rather as an evolutionary process with new techniques; research and development in search for better practices and product improvement should be emphasised."

The manufacturing process is one of the key steps where quality control is required to ensure the quality of the final product. Good Manufacturing Practices (GMP) is one of the most important tools for this measure.

Dr. Nyombaire provides five steps to ensure quality of traditional medicines:

- Apply the World Health Organization technical guidelines in regard to safety and efficacy of traditional medicines.
- Conduct regular training of manufacturers and vendors of traditional medicines on Good Agriculture Practices and Good Manufacturing Practices.
- Establish small industries in different areas of the country where manufacturers may learn how to produce improved traditional medicines.
- Establish a Rwandan Advisory Committee for traditional medicine to help in the implementation of traditional medicine policy
- Avail suitable equipment, chemicals and reference compounds for quality control of traditional medicines.

Indeed, some of the challenges faced include lack of knowledge on Good Agriculture Practices and Good Manufacturing Practices of traditional medicine; regulations of traditional medicine, laboratory for toxicity and efficacy assessment; high cost of reference compounds used for quality control of traditional medicines, or lack of data on fingerprints of flora of Rwanda.

Consequently, the quality of traditional medicines needs to be **improved** through research for the safety of consumers

DEVELOPMENT OF TRADITIONAL MEDICINE

However, the policy and will of the Government of Rwanda through the Ministry of Health gives light to the future of traditional medicine. The 'Made in Rwanda' policy that promotes locally made products also provides room for improvement and development of the traditional medicine domain.

NIRDA statistics indicate that more than 75 per cent of Rwandans use herbs as alternative medicines.

Availability of botanical gardens of medicinal plants is also noted among opportunities in promoting traditional medicines.

NIRDA statistics indicate that more than **75 per cent of Rwandans** use herbs as alternative medicines

The particularity lies also in some evidences on effectiveness of the local plants such as Umuravumba and Inyabarasanya. There is also a National Herbarium for medicinal plants identification.

Traditional health practitioners have also expressed readiness to share the recipes of their drugs taking into consideration the intellectual property, so that those herbals are tested to identify the exact amount to administer and also to be advised on how to conserve their drugs for long period.

Dr. George Nyombaire also has a message for manufacturers and traders or vendors of traditional medicines as well as to consumers.

“It is important to apply good manufacturing practices in processing and to ensure that manufacturers have knowledge on traditional medicines processing and preservation. It is also important to obtain quality and toxicological tests of traditional medicines before selling them to consumers, but retailers should also have enough knowledge on the use of traditional medicines based on scientific evidences for effectiveness and safety of any medicinal plant they use,” says Dr. Nyombaire.

No doubt, medicinal plants are endangered. According to a research conducted by AGA Rwanda Network, an association of traditional healers in the country, over 700 medicinal plant species are in danger of decline.

AGA Rwanda network has over 3,000 registered healers. Overall, there are about 14,000 traditional healers countrywide.

Consumers, Dr Nyombaire observes, should not accept any traditional medicine that is unhygienic or in any bad condition since some people claiming to be traditional health practitioners are doing it only for business without any scientific knowledge of traditional medicine.

RWANDA APPROVED STANDARDS ON AFRICAN

TRADITIONAL MEDICINE

On 25th May, 2016, Rwanda hosted the African Regional Standardization Organization (ARSO) Technical Harmonization Committee (ARSO/THC 13) meeting on African Traditional Medicine. The meeting was held in Kigali and saw the participation of members from 16 countries across Africa.

By definition, "traditional" use of herbal medicine implies substantial historical use, and this is certainly true for many products that are available as "traditional herbal medicine". In many developing countries, a large proportion of the population relies on traditional practitioners and their armamentarium of medicinal plants in order to meet health care needs. Although modern medicine exists it seats side-by-side with such traditional practice as herbal medicine has often maintained its popularity for historical and cultural reasons.

ARSO/THC/13 was tasked to prepare African Standards (ARS) with particular emphasis on quality and safety of African Traditional Medicine (ATM) to facilitate regional and international trade with an initial focus on terminology, raw material and processed products specifications. This meeting was crucial in that it was an occasion to unveil the 10 needed ATM standards that would enhance improved product competitiveness and access to export markets.

The meeting also convened at a time when the demand for quality and safety of African Traditional Medicine (ATM) and mainstreaming in the African National Health care systems through standardization and proper regulation has been ever increasing. This also impacts on the livelihoods of the majority of consumers as studies have indicated that 80 – 90 % of people in Africa depend on traditional medicine for their primary healthcare (Christian, 2009; Scott et al., 2004; and World Health Organization (WHO, 2003) and that the demand for herbal medicine is growing between 10 % to 20 % annually across the world. It is also estimated that the global trade in traditional medicine has been estimated at US$ 83 billion.

Considering the role of traditional medicine standards in national health system especially in promoting the visibility, viability, applicability and modern favorable attitudes among African populations in general and Rwandans in particular, enhancing their benefits to patients and the broader community in general.

The purpose of setting regional standards for African traditional medicine is to:

- Provide scientific information on the safety, efficacy, and quality control/quality assurance of widely used African medicinal plants, in order to facilitate their appropriate use and trade within the country and Member States;
- Provide models to assist African Countries in developing their own traditional medicine or formularies for these or other herbal medicines;
- Facilitate information exchange among Member States of ARSO; and
- Develop robust standards and other deliverables relevant to African traditional medicine:
    I. generic standards;
    II. specific standards;
    III. codes of practice;
    IV. monographs;
    V. certification and regulatory guidelines; and
    VI. Other standards and deliverables relevant to ATM.

The Meeting brought together participants/ Technical Committee Members from the National Standards Bodies, Regulatory Agencies, Academia, Research institutions and the Private Sector from ARSO Member States to consider ARSO Final Draft Standards for Traditional Medicine.

The Committee has 17 active Member States namely ; (1) Rwanda, (2) Burkina Faso, (3) DR Congo, (4) Egypt, (5) Ethiopia, (6) Gabon, (7) Ghana, (8) Kenya, (9) Mauritius, (10) Nigeria; (10) Botswana; (12) Senegal; (13) South Africa; (14) Sudan; (15) Tanzania; (16) Zambia, (17) Zimbabwe and two observer Member States of Seychelles and Tanzania.

The Member States are represented in the Technical Harmonization Committee by their National Standards Bodies.

In September 2017, through the approval by RSB Board of Directors, Rwanda adopted the ten African Traditional Medicine standards, pursuant to their approval at continental level. Those standards include:

STANDARDS FOR AFRICAN TRADITIONAL MEDICINE

1	RS ARS 950: 2016	African Traditional Medicine — Terms and terminology
2	RS ARS 951: 2016	African Traditional Medicine — Good manufacturing practices (GMP) for herbal medicines
3	RS ARS 952: 2016	African Traditional Medicine — Requirements on good agricultural and collection practices (GACP) for medicinal plants
4	RS ARS 953: 2016	Traditional African Medicine — Certification scheme for medicinal plant produce
5	RS ARS 954: 2016	African Traditional Medicine — Minimum requirements for registration of plant based traditional medicines
6	RS ARS 955: 2016	African Traditional Medicine — Technical guidelines for safety, efficacy and quality of raw materials and herbal medicines
7	RS ARS 956-1: 2016	African Traditional Medicine — Medicinal plant standards — Aloe vera
8	RS ARS 956-2: 2016	African Traditional Medicine — Medicinal plant standards — Ambrosia maritima
9	RS ARS 956-3: 2016	African Traditional Medicine — Medicinal plant standards — Urtica dioica and Urtica urens
10	RS ARS 956-4: 2016	African Traditional Medicine — Medicinal plant standards — Calotropis procera

Beneficiaries of those standards include but not limited to members of regulatory authorities, practitioners of traditional medicine, practitioners of orthodox, pharmacists, other health professionals, manufacturers of herbal products, and research scientists.

In some countries, herbal medicine is subject to rigorous manufacturing standards. However, this is not the case everywhere. In Rwanda, for example, where herbal products are sold as “phytomedicine”, they are subject to the same criteria for efficacy, safety and quality as are other drug products.

So far, the Council of Traditional Medicine Practitioners under the Ministry of Health is in place and Traditional Medicine Practitioners are encouraged to register.

Rwanda Standards Board

ISO 9001 Certified

Rwanda Standards Board

ISO 9001 Certified