



**GUIDELINES FOR THE IMPLEMENTATION OF MARK-UPS
ACROSS THE PHARMACEUTICAL SUPPLY AND
DISTRIBUTION CHAIN**

AUGUST, 2025

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA), established pursuant to Law No. 003/2018 of 09/02/2018, is vested with the primary mandate of safeguarding public health. This responsibility is carried out through the regulation of human and veterinary medicines, vaccines, biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco, and tobacco products. Integral to this mandate is the regulation of pharmaceutical product pricing to ensure affordability and equitable access for all citizens of Rwanda.

In alignment with the National Health Sector Strategic Plan 2024–2029, which aims to achieve universal access to quality and affordable medicines by 2029, the Ministry of Health mandated Rwanda FDA to implement the National Pharmaceutical Product Pricing and Cost Containment Policy (October 2020). This policy includes the establishment of the Pharmaceutical Pricing Advisory Committee (PPAC) and the setting maximum allowable mark-ups and reference prices for both imported and locally manufactured pharmaceuticals.

Under Technical Regulations No. ODDG/RES/TRG/003, Rwanda FDA issues Guidelines No ODDG/RES/GDL/001, establishing a framework for applying and monitoring mark-ups across the pharmaceutical supply chain. These Guidelines provide a direction for the implementation of maximum mark-ups, introduce regressive mark-ups for high-cost medicines to promote pricing equity, and fulfil Rwanda FDA's obligations under Law No. 003/2018.

Rwanda FDA expresses its appreciation to all stakeholders, including the Ministry of Health, private sector partners and consumer representatives, for their contribution to the development and validation of these Guidelines. Their collaboration has been instrumental in shaping a robust framework for pharmaceutical pricing regulation.

Rwanda FDA remains committed to ensuring the safety, effectiveness, and affordability of medicines for all Rwandans.

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Director General



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ACCRONYMES AND ABBREVIATIONS

BNR	Banque Nationale du Rwanda
BUFMAR	Bureau des Formations Médicales Agréées in Rwanda
GDP	Gross Domestic Product
PO	Purchase Order
PPAC	Pharmaceutical Pricing Advisory Committee
PPP	Purchasing Power Parity
RMS Ltd	Rwanda Medical Supply Limited
Rwanda FDA	Rwanda Food and Drugs Authority
SRP	Suggested Retail Price
WHO	The World Health Organization

GLOSSARY / DEFINITIONS

In these Guidelines, unless the context otherwise requires:

“Authority” means Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under Article 2 of the Law No. 003/2018 of 09/02/2018.

“Biological product” means a medicine produced from living sources such as humans, animals, bacteria, viruses or fungus, or produced by using advanced biotechnology.

“Controlled drug or controlled medicine” means any narcotic drug, psychotropic substance or precursors as listed under Law N°03/2012 of 15/02/2012 governing narcotic drugs, psychotropic substances and precursors in Rwanda;

“Essential medicines” refers to medicines that satisfy the priority health care needs of the population, and are selected based on the evidence of their efficacy, safety, and comparative cost-effectiveness.

“Ex-manufacturer price” means the price of a product set by the manufacturer at the factory gate, before adding taxes, transport, or distributor/retailer mark-ups.

“Expensive medicine” means pharmaceutical products whose monthly cost exceeds the monthly gross domestic product per capita (GDP per capita, PPP).

“Fixed cost or fixed fee” means a set fee that does not vary according to the cost of the item to which it is being applied.

“Importer” means a company or entity that brings pharmaceutical goods, such as medications, vaccines, medical devices, and other healthcare-related products, into a country from another country for commercial purposes. This includes the owner of the pharmaceutical products.

“Mark-up” means the additional charges and costs that are applied to the price of a commodity to cover overhead costs, distribution charges, and profit or surplus.

“Medical product” means all products used for medical purposes, including medicinal products, medical devices, in vitro diagnostics, and biologicals, intended for diagnosis, prevention, monitoring, treatment, or alleviation of disease.

“Over-the-counter (OTC)” means a medicine that can be bought directly from a pharmacy, shop, or supermarket without a doctor’s prescription, because it is considered safe and effective for use by the general public when taken as directed.

“Overhead cost” refers to the ongoing expense of operating a business. Overheads are the expenditure which cannot be conveniently traced to or identified with any particular cost unit, unlike operating expenses such as raw materials and labour.

“Pharmaceutical pricing policies” means a set of written principles or requirements for managing the prices of pharmaceutical products, agreed or adopted by a public institution (e.g. a government), a group of purchasing organizations or individual health services.

“Pharmaceutical product (medicine)” means any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also includes products used in disinfecting premises in which food and medicines are manufactured, prepared or stored, and in cleaning hospitals, equipment and farm houses.

“Pharmacist” means any person authorized to make or dispense a medicine by virtue of his/her academic qualification under the Law No 45/2012 of 14/01/2013 on the organization, functioning and competence of the Council of Pharmacists;

“Pharmacy only medicines” means all non-prescription medicines other than general sales medicines;

“Prescription only medicines” means any drug product required to be dispensed only upon a prescription given by a veterinarian, medical practitioner, dentist or any other person approved by the Minister;

“Prescription” means a lawful written direction by a medical practitioner, dentist or veterinary surgeon for the preparation and dispensing of a drug by a pharmacist;

“Psychotropic substances” means any natural or synthetic substance, material, salt, or preparation referred to in the Convention on Psychotropic Substances of 1971, intended for medical and scientific purposes;

“Public Price (the price of selling the medicine to the public)” means the wholesale price of the medicine plus the pharmacy mark-up.

“Regressive mark-up” means a mark-up whereby the size or value of the mark-up decreases as the price of the product increases. This may be on a sliding scale or applied in differential (discrete) steps according to threshold prices.

“Scheduling” means a national classification system that controls how medicines and chemicals are made available to the public;

“Wholesale price” means the export / factory price plus the profit percentage of the medicine trade warehouse.

CHAPTER I. GENERAL INTRODUCTION

I.1 Introduction

Rwanda Food and Drugs Authority (Rwanda FDA) has made significant strides in enhancing the affordability of essential medicines as part of its broader commitment to protecting and improving public health. Established under Law No. 003/2018, Rwanda FDA is mandated to regulate the pricing of pharmaceutical products to ensure prices are fair, reasonable, and accessible to all Rwandans.

In line with this mandate, the Pharmaceutical Product Pricing and Cost Containment Policy were adopted in 2020 to provide strategic direction for regulating medicine prices and managing pharmaceutical expenditures.

As part of its implementation, two foundational regulations have been approved: the regulations on maximum mark-up on human medicinal products and the regulations on reference pricing on human medicinal products. these regulations form a legal and operational framework for setting maximum allowable mark-ups, establishing reference prices, and promoting consistency in pricing practices across the pharmaceutical supply chain. they outline detailed procedures and methodologies for determining pharmaceutical product prices.

However, challenges remain, particularly due to limited interventions in effectively regulating prices and containing costs. it is recommended that mark-up regulations be implemented in combination with other pharmaceutical pricing policies and with emphasis on the adoption of regressive mark-up structures, where the percentage mark-up decreases as the product price increases. this approach promotes equity and discourages excessive pricing of high-cost medicines.

I.2 Why Regressive Mark-Up

A regressive mark-up structure ensures that higher-priced medicines do not become disproportionately expensive due to fixed percentage mark-ups. By applying lower mark-up rates to higher-cost products, this method prevents inflation of already expensive medicines, thereby maintaining affordability.

At the same time, it allows for slightly higher mark-ups on lower-priced products to ensure business viability across the supply chain. This structure strikes a balance between protecting patients from excessive costs and sustaining pharmaceutical sector viability.

Findings from the 2019 Technical Report on the Pharmaceutical Pricing and Cost Containment Policy revealed several challenges in Rwanda's pharmaceutical sector, including but not limited to:

- a. Limited government oversight of manufacturers' prices;
- b. Significant variation in pharmaceutical prices;
- c. Lack of transparency in pricing across the supply chain;
- d. Potential for cumulative mark-ups due to multiple wholesalers; etc.

In response to these challenges, Rwanda FDA has developed Guidelines on Pharmaceutical Product Mark-Ups. These Guidelines aim to support all stakeholders particularly business and economic operators in understanding how Rwanda FDA regulates mark-ups on approved pharmaceutical prices. They provide up-to-date guidance on the principles and methodologies used to ensure that medicine prices across the supply chain are fair, transparent, and justifiable.

Focusing specifically on ex-manufacturer prices for medicines supplied to the retail sector or procured through public tender, the Guidelines establish a structured framework that promotes affordability and safeguards public health.

They define and regulate maximum selling prices by introducing a regressive mark-up structure, applying lower mark-up rates to higher-priced products. By clarifying pricing procedures and encouraging compliance, these Guidelines contribute to the establishment of a more accessible, affordable, and sustainable healthcare system for all Rwandans.

I.3 Legal Basis for implementing for the Guidelines

The legal basis for implementing these Guidelines is as follows:

- a. Rwanda FDA Law N° 003/2018 of 09/02/2018, establishing Rwanda FDA, determining its mission, organization and functioning especially in its articles 8 and 9.
- b. Regulations Governing the Maximum Mark-up of Human Medicinal Products (ODDG/RES/TRG/003 Version_1).
- c. Regulations Governing Internal and External Reference Pricing of Human Medicinal Products (ODDG/RES/TRG/002 Version_1).

I.4 Rationale for the Guidelines

These Guidelines are designed to protect patients and other key stakeholders in the pharmaceutical supply chain from excessive mark-ups and unjustified charges that may be added to the prices of medicines and other medical products. By setting clear rules and limits, the Guidelines aim to promote fair pricing practices and ensure that these products remain affordable and accessible to everyone.

I.5 Scope

These Guidelines shall apply to all stakeholders involved in the pharmaceutical supply and distribution chain in Rwanda, including manufacturers, wholesalers, distributors, retailers, and both public and private healthcare facilities. The Guidelines cover both general and regressive mark-ups on medicines and other medical products. These Guidelines specifically address ex-manufacturer prices and import prices.

While the general mark-ups apply to all medicines and other medical products on the Rwandan market, regressive mark-ups are applied only to a selected list of medicines and other medical products. The medicines subject to regressive markups were selected from the medicines schedule of prescription only medicines (POM).

There are three medicinal schedules that apply in the Rwandan context: Controlled Medicines (CM), Prescription-Only Medicines (POM), and Over-the-Counter Medicines (OTC) are explained below:

- a. **Controlled medicines:** Psychotropic substances, including new psychotropic substances (NPS) and those used for medical purposes, are essential to prevent abuse, misuse, and dependence. However, since many controlled substances have ongoing medical applications, it is necessary to ensure continued access for patients in need.
- b. **POM (Prescription-Only Medicine):** Medicines that can only be dispensed with a prescription from a qualified health professional.
- c. **OTC (Over-The-Counter):** A pharmaceutical which may be dispensed without a prescription. In some countries they are available via self-service in pharmacies and/or other retail outlets (e.g. Drugstores).

The following figure shows how these schedules integrate practically in the Rwandan system.

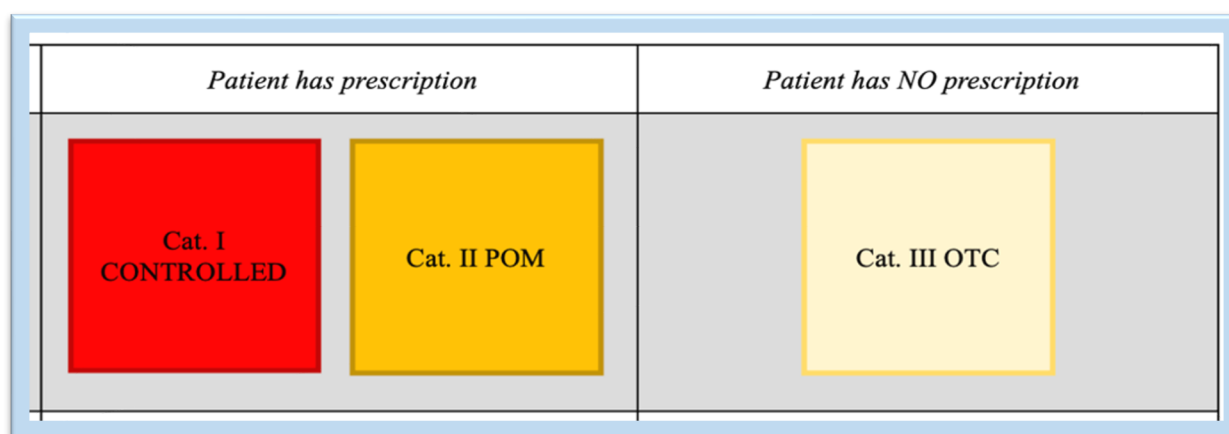


Figure 1: Medicine categories in Rwanda based on schedules ¹

All medicines including those classified as Over-the-Counter (OTC) medicines are required to be dispensed exclusively through licensed pharmacies. This policy ensures that even basic health products are made available under the supervision of qualified pharmacists, thereby safeguarding public health and ensuring proper guidance in their use.

Color legend: Red (Cat. I): Controlled medicines with the highest level of restriction., Orange/Amber (Cat. II): Prescription-only medicines (POM). Light Yellow (Cat. III OTC): Over-the-counter medicines available without prescription.

CHAPTER II. METHODOLOGY

A general mark-up scheme has been established in the regulations to provide a standardized approach to pricing across all pharmaceutical products. However, based on international literature, data analysis, and stakeholder consultations, a more detailed regressive mark-up scheme has been developed and included in these Guidelines. This scheme offers a more equitable pricing mechanism, particularly for high-cost medicines and medical products.

II.1 General Mark-Up Schemes

According to Rwanda FDA regulations, the general mark-ups outlined in these Guidelines represent the maximum allowable limits for each sector, i.e. public wholesale, public retail, private wholesale, and private retail. Suppliers or vendors of pharmaceutical products must not apply mark-ups that exceed these limits.

A supplier or vendor may apply any mark-up that is equal to or lower than the maximum mark-up set out in the Guidelines, depending on the sector in which they operate. The maximum mark-up applies to the import price for imported pharmaceutical products and to the purchase price for locally sourced products.

In summary, the maximum allowable mark-up shall be calculated based on the import price (or local manufacturing price for locally produced products) as per the below:

Table 1: General mark-up at all pharmaceutical supply chain levels

MAX MARKUP	Wholesale Markup (add-on percentage)	Retail Markup (add-on percentage)
Public	20,0%	20,0%
Private	25,0%	33,5%

The applicable mark-up rates are published on the Rwanda FDA website and updated as necessary during periodic reviews.

Public wholesalers include Central Medical Stores, which are wholesale pharmacies that supply the public healthcare sector in Rwanda. These include Rwanda Medical Supplies (RMS Ltd), Bureau des Formations Médicales Agréées in Rwanda (BUFMAR), and Mediasol Pharmaceutical depot Ltd. Based on available evidence and after careful consideration of the Pharmaceutical Advisory Committee (PPAC) recommendations, the maximum mark-up for Central Medical Stores is set at **20%**.

Private wholesalers' general mark-up is set at a maximum of **25%**, based on available evidence and after careful consideration of the PPAC recommendations.

Public retailers include public hospitals, health canterers, and health posts. Based on available evidence and after careful consideration of the PPAC recommendations, the maximum mark-up for these entities is set at **20%**.

Private retailers include private pharmacies and pharmacies in private Hospitals. Based on available evidence and after careful consideration of the PPAC recommendations, the maximum mark-up for retail pharmacies is set at **33.5%**. This mark-up applies to the purchase price of pharmaceutical products.

II.2 Regressive Mark-up Schemes

Regressive mark-ups are designed to shift the pricing burden in a way that promotes affordability. Under this model, lower-cost medicines and other medical products are subject to higher percentage mark-ups, while more expensive ones have lower mark-ups.

This approach helps reduce the price gap between essential and non-essential products, making essential treatments more accessible to patients. It is aligned with international best practices, including guidance from the World Health Organization (WHO), which emphasizes fair and equitable pricing to ensure universal access to life-saving treatments.

Currently, the application of regressive mark-ups is limited to specific categories of medicines and medical products. This limitation is based on the principle of medicinal scheduling, where products are classified according to factors such as therapeutic importance, cost, and availability. Only those medicines and medical products deemed critical are included in the regressive mark-up system to ensure the Guidelines address the most urgent healthcare needs.

To account for differences across the supply chain, a specific regressive mark-up schedule has been developed for each sector i.e. public or private, wholesale or retail. These schedules reflect the distinct pricing structures and operational realities of each market segment, ensuring that the application of regressive mark-ups remains both practical and effective.

The following four tables outline the detailed regressive mark-up rates across different categories and sectors:

Table 2: Regressive mark-up for public wholesalers

MAXIMUM MARK-UP general		20.00%				
Regressive Mark-Up Scheme for Central Medical Stores - RMS Ltd, BUFMAR & Mediasol when operating in the public sector						
Import Price/Domestic production price MIN (in FRW)	Import Price/Domestic production price MAX (in FRW)	Maximum Mark-Up	Wholesale Price for lowest import price in this range	Wholesale Price for highest import price in this range	Wholesale Margin for lowest import price in this range	Wholesale Margin for highest import price in this range
-	18,000.00	20.0%	-	21,600.00	-	3,600.00
18,000.01	19,429.00	3,400.00	21,400.01	22,829.00	3,400.00	3,400.00
19,429.01	40,000.00	17.5%	22,829.09	47,000.00	3,400.08	7,000.00
40,000.01	46,670.00	7,000.00	47,000.01	53,670.00	7,000.00	7,000.00
46,670.01	80,000.00	15.0%	53,670.51	92,000.00	7,000.50	12,000.00
80,000.01	96,000.00	12,000.00	92,000.01	108,000.00	12,000.00	12,000.00
96,000.01	200,000.00	12.5%	108,000.01	225,000.00	12,000.00	25,000.00
200,000.01	250,000.00	25,000.00	225,000.01	275,000.00	25,000.00	25,000.00
250,000.01	400,000.00	10.0%	275,000.01	440,000.00	25,000.00	40,000.00
400,000.01	533,340.00	40,000.00	440,000.01	573,340.00	40,000.00	40,000.00
533,340.01	1,000,000.00	8.0%	576,007.21	1,080,000.00	42,667.20	80,000.00
1,000,000.01		7.5%	75,000.00	IP/DPP + 75,000.00	7.5%	8%
Note: To avoid any drops and jumps there are stand-still areas.			IP/DPP = import price/domestic production price + cap			
Note: All products in this category priced above 1,000,000.01 shall be subject to a maximum mark-up of 7.5%.						

Table 3: Regressive mark-up for public retailers (public health facilities)

MAXIMUM MARK-UP general		20.00%				
Regressive Mark-Up Scheme for Public Health Facilities						
Wholesale Price (=Retail Purchase Price) MIN (in FRW)	Wholesale Price (=Retail Purchase Price) MAX (in FRW)	Maximum Mark-Up	Retail Price for lowest wholesale price in this range	Retail Price for highest wholesale price in this range	Retail Margin for lowest wholesale price in this range	Retail Margin for highest wholesale price in this range
-	21,600.00	20.0%	-	25,920.00	-	4,320.00
21,600.01	23,315.00	4,320.00	25,920.01	27,635.00	4,320.00	4,320.00
23,315.01	47,000.00	17.5%	27,395.14	55,225.00	4,080.13	8,225.00
47,000.01	54,834.00	8,225.00	55,225.01	63,059.00	8,225.00	8,225.00
54,834.01	92,000.00	15.0%	63,059.11	105,800.00	8,225.10	13,800.00
92,000.01	110,400.00	13,800.00	105,800.01	124,200.00	13,800.00	13,800.00
110,400.01	225,000.00	12.5%	124,200.01	253,125.00	13,800.00	28,125.00
225,000.01	250,000.00	28,125.00	253,125.01	278,125.00	28,125.00	28,125.00
250,000.01	440,000.00	10.0%	275,000.01	484,000.00	25,000.00	44,000.00
440,000.01	533,340.00	44,000.00	484,000.01	577,340.00	44,000.00	44,000.00
533,340.01	1,080,000.00	7.5%	573,340.51	1,161,000.00	40,000.50	81,000.00
1,080,000.01		7%	IP/DPP + 75,000.00	IP/DPP + 75,000.00	7%	7%
Note: To avoid any drops and jumps there are stand-still areas.			IP/DPP = import price/domestic production price + cap			
Note: All products in this category priced above 1,080,000.01 shall be subject to a maximum mark-up of 7%.						

Table 4: Regressive mark-up for private wholesalers

MAXIMUM MARK-UP general		25.0%				
Regressive Mark-Up Scheme for private wholesalers						
Import Price/Domestic production price MIN (in FRW)	Import Price/Domestic production price MAX (in FRW)	Maximum Mark-Up	Wholesale Price for lowest import price in this range	Wholesale Price for highest import price in this range	Wholesale Margin for lowest import price in this range	Wholesale Margin for highest import price in this range
-	18,000.00	25.0%	-	22,500.00	-	4,500.00
18,000.01	19,320.00	4,250.00	22,250.01	23,570.00	4,250.00	4,250.00
19,320.01	40,000.00	22.0%	23,570.41	48,800.00	4,250.40	8,800.00
40,000.01	48,000.00	8,800.00	48,800.01	56,800.00	8,800.00	8,800.00
48,000.01	80,000.00	18.5%	56,880.01	94,800.00	8,880.00	14,800.00
80,000.01	95,484.00	14,800.00	94,800.01	110,284.00	14,800.00	14,800.00
95,484.01	200,000.00	15.5%	110,284.03	231,000.00	14,800.02	31,000.00
200,000.01	258,340.00	31,000.00	231,000.01	289,340.00	31,000.00	31,000.00
258,340.01	400,000.00	12.0%	289,340.81	448,000.00	31,000.80	48,000.00
400,000.01	505,270.00	48,000.00	448,000.01	553,270.00	48,000.00	48,000.00
505,270.01	1,000,000.00	10.0%	555,797.01	1,100,000.00	50,527.00	100,000.00
1,000,000.01		9%	1,090,000.01	9%	90,000.00	9%
Note: To avoid any drops and jumps there are stand-still areas.						
Note: All products in this category priced above 1,000,000.01 shall be subject to a maximum mark-up of 9%.						

Table 5: Regressive mark-up for private retailers

MAXIMUM MARK-UP general		33.5%				
Regressive Mark-Up Scheme for private retailers (Private Health Facilities, Retail Pharmacies)						
Wholesale Price (=Retail Purchase Price) MIN (in FRW)	Wholesale Price (=Retail Purchase Price) MAX (in FRW)	Maximum Mark-Up	Retail Price for lowest wholesale price in this range	Retail Price for highest wholesale price in this range	Retail Margin for lowest wholesale price in this range	Retail Margin for highest wholesale price in this range
-	22,500.00	33.5%	-	30,037.50	-	7,537.50
22,500.01	24,548.00	7,537.50	30,037.51	32,085.50	7,537.50	7,537.50
24,548.01	48,800.00	29.0%	31,666.93	62,952.00	7,118.92	14,152.00
48,800.01	56,610.00	14,152.00	62,952.01	70,762.00	14,152.00	14,152.00
56,610.01	94,800.00	25.0%	70,762.51	118,500.00	14,152.50	23,700.00
94,800.01	112,860.00	23,700.00	118,500.01	136,560.00	23,700.00	23,700.00
112,860.01	231,000.00	21.0%	136,560.61	279,510.00	23,700.60	48,510.00
231,000.01	285,353.00	48,510.00	279,510.01	333,863.00	48,510.00	48,510.00
285,353.01	448,000.00	17.0%	333,863.02	524,160.00	48,510.01	76,160.00
448,000.01	609,280.00	76,160.00	524,160.01	685,440.00	76,160.00	76,160.00
609,280.01	1,100,000.00	12.5%	685,440.01	1,237,500.00	76,160.00	137,500.00
1,100,000.01	1,368,750.00	137,500.00	1,237,500.01	1,506,250.00	137,500.00	137,500.00
1,368,750.01		10.0%	1,505,625.01	10.0%	136,875.00	10%
Note: To avoid any drops and jumps there are stand-still areas.						
Note: All products in this category priced above 1,368,750.01 shall be subject to a maximum mark-up of 9%.						

II.3 Applicability of general and regressive mark-ups

The general mark-up regulations have been published, establishing a framework for regulating pharmaceutical prices. However, challenges persist in controlling the costs of high-priced medical products, including certain medicines, as the current mark-up structure may not adequately address the pricing of these more expensive items.

To mitigate these challenges, stricter regressive mark-ups shall be applied to specific groups of medicines. These schemes complement the general mark-up system by adjusting the allowable mark-up percentages based on import prices or local production costs, offering a more targeted and equitable approach to managing the prices of high-cost medical products.

The table below presents the mark-up rates assigned to each category of medicines, indicating whether general or regressive mark-ups apply, as defined in the approved schedules:

Table 6: Markup applicability to medicinal schedule

Schedule	General mark-ups apply	Regressive mark-up schemes apply
Cat. I - C	Yes, for medicinal use products.	No, not currently, subject to change upon review of the Guidelines.
Cat. II - POM	Yes, for all medicines in this group (Except for products classified as critical).	Yes, for products classified as critical
Cat. III - OTC	Yes, for all OTC.	Not applicable for this category

The following groups of POM were selected for the application of regressive mark-ups:

- a. Anticancer drugs;
- b. Antidiabetics drugs;
- c. Cardiovascular drugs;
- d. Biologicals² other than vaccines (e. g. Enzyme Replacement Therapy, etc);
- e. Hormones and hormone modifiers;
- f. Orphan drugs³,
- g. Inhalers and injectables used for treatment of Obstructive Lung Diseases;
- h. Immunosuppressant/ immunomodulatory drugs.

Beyond the medicinal products detailed in these documents, regressive mark-ups shall be applicable to other categories of medical products. These include medical devices, in vitro diagnostics, and biologicals used for diagnosis, prevention, monitoring, treatment, or alleviation of diseases, as defined under the broader term “medical products.”

² **Biologicals:** Vaccines, blood-derived medicines and other blood products, gene therapy medicines; tissues, cells, peptides, polypeptides, and other biological materials used for therapeutic, prophylactic, or diagnostic purposes.

³ **Orphan drugs:** are medicinal products developed specifically to treat rare diseases or conditions, often called **orphan diseases**, which affect a small percentage of the population and because due to its limited market, it is unlikely to be adopted by a pharmaceutical company.

Where applicable, these non-medicinal medical products shall be subject to regressive mark-up regulations to ensure fair and consistent pricing across the healthcare sector.

CHAPTER III: ADDITIONAL INFORMATION

Some additional information needs to be taken into consideration when applying the general and regressive markups:

- a. The level of mark-up shall remain fixed per unit, irrespective of the quantity supplied. Mark-ups are strictly product-based and not volume-dependent.
- b. From the point of importation or manufacturing to the final patient, mark-ups shall only be applied at two levels: one at the wholesale level and one at the retail level, depending on the distribution sector (public or private).
- c. These Guidelines support the establishment of maximum patient prices, which shall be calculated in accordance with the applicable mark-ups across different sectors (public or private).
- d. In the event of a declared pandemic, public health emergency, or other natural disasters, the government reserves the right to impose price control measures, including a price freeze and/or suggested retail prices for affected medicines and related commodities. These measures shall apply to products identified by the Ministry of Health, in coordination with its affiliated agencies. In such cases, the following provisions shall be observed:
 - i. Temporary Suspension or Adjustment of Mark-Ups: The applicable wholesale and retail mark-ups may be temporarily suspended, reduced, or adjusted to ensure affordability and accessibility of essential medical products.
 - ii. Mandatory Price Reporting: All stakeholders involved in the supply chain i.e importers, manufacturers, wholesalers, and retailers, shall be required to submit updated price information for the identified products within a timeframe specified by the Ministry of Health or its designated agency.
 - iii. Enforcement and Monitoring: Rwanda FDA, in collaboration with relevant regulatory bodies, shall implement monitoring and enforcement mechanisms to ensure compliance with temporary price control measures.
 - iv. Duration and Review: These emergency pricing measures shall remain in effect for the duration of the declared crisis and shall be subject to periodic review and revocation once normal market conditions resume.
 - v. Transparency and Communication: All changes in pricing regulations or emergency pricing decisions shall be communicated promptly and transparently to all stakeholders and the public to ensure clarity, compliance, and accountability.
 - vi. Price Freeze: No changes to retail prices are allowed. The prevailing price prior to the pandemic or other emergency situations shall continue to apply.
 - vii. Suggested Retail Price (SRP): If the prices indicated in the SRP, as determined by contracts or agreements between the government and suppliers, differ from the rates established in these Guidelines, the lower price shall prevail.

III.1 Review of the Guidelines

The Guidelines shall be reviewed and updated on a regular basis, or as often as deemed necessary by Rwanda FDA, taking into account the following considerations:

- a. The need to ensure the continued availability, accessibility, and affordability of quality-assured medicines and scheduled substances in the country;
- b. Annual inflation rates and other relevant macroeconomic indicators published by the National Bank of Rwanda (BNR);
- c. Market intelligence and pricing data provided by pharmacists and other supply chain actors, in accordance with reporting requirements set by Rwanda FDA;
- d. Recommendations or directives from the Ministry of Health, including any public health priorities or emerging challenges;
- e. Regional and international pricing trends, including reference pricing mechanisms and procurement benchmarks;
- f. Feedback from stakeholders gathered through consultations, surveys, or monitoring and evaluation activities; and
- g. Any unforeseen circumstances or emergencies (e.g., pandemics, supply disruptions) that may warrant urgent regulatory adjustments.

In any case, and no later than one year after the implementation of these Guidelines, a comprehensive evaluation and review shall be conducted based on data analysis and feedback from all relevant stakeholders. This process will aim to assess the effectiveness, challenges, and impact of the Guidelines, with a view to making necessary adjustments for improved implementation and outcomes.

III.2 Enforcement, Sanctions and non-compliance

Rwanda FDA will monitor compliance with these Guidelines through regular audits, market surveillance, and stakeholder engagement. Non-compliance with maximum mark-up regulations will result in penalties as outlined in the Law N° 003/2018 of 09/02/2018, establishing Rwanda FDA, determining its mission, organization and functioning especially in its articles 9 and related technical regulations. A reporting mechanism will be established to allow stakeholders and consumers to report pricing violations.

Rwanda FDA will collaborate with pharmaceutical manufacturers, distributors, healthcare providers, and consumer groups to ensure effective implementation of these Guidelines. Stakeholder feedback will be incorporated through regular consultations and validation workshops.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	Division Manager for Regulatory Ecosystem Strategy	Division Manager for QMS	Deputy Director General	Director General
Names	Mr. Jose Edouard MUNYANGAJU	Ms. Marie Ange UWASE	Ms. Martine UMUHOZA	Prof. Emile BIENVENU
Date & Signature	 Jose Edouard Munyangaju 2025.08.29 14:50:08 +02'00' 2025.001.20630	 Digitally signed by Marie Ange UWASE Date: 2025.08.29 15:00:01 +02'00'	For  Digitally signed by Rwanda FDA(Head of Department) Date: 2025.08.29 15:47:20 +02'00'	 Digitally signed by RWANDA FDA(Director General) Date: 2025.08.30 13:37:43 +02'00'

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APPENDICES

APPENDIX 1: REGRESSIVE MARK-UP SCHEMES APPLICATION

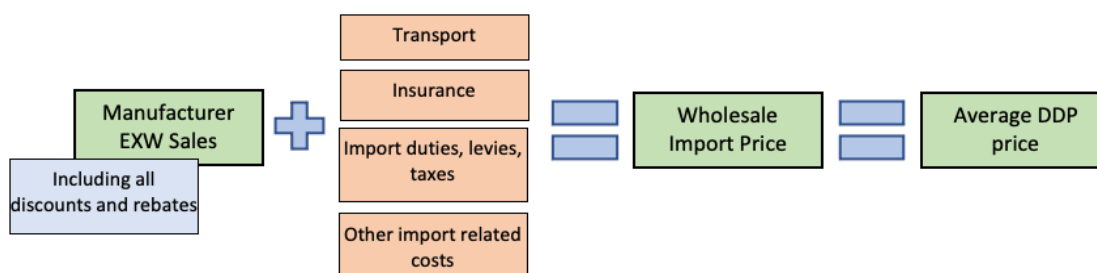
Regressive mark-up schemes application			
	Import Price/Local Production Price (IP/LPP)		Insert IP/LPP
RM	MAX PRICES	Wholesale Price (=Retail Purchase Price)	Retail Price (Consumer Price)
	Public	–	–
	Private	–	–
	MAX MARGIN	Wholesale Margin (=Wholesale Service Fee)	Retail Margin (=Retail Service Fee)
	Public	–	–
	Private	–	–
	MAX MARKUP	Wholesale Markup (add-on percentage)	Retail Markup (add-on percentage)
	Public	–	–
	Private	–	–
Comparison to general mark-up application			
GM	MAX PRICES	Wholesale Price (=Retail Purchase Price)	Retail Price (Consumer Price)
	Public	–	–
	Private	–	–
	MAX MARGIN	Wholesale Margin (=Wholesale Service Fee)	Retail Margin (=Retail Service Fee)
	Public	–	–
	Private	–	–
	MAX MARKUP	Wholesale Markup (add-on percentage)	Retail Markup (add-on percentage)
	Public	–	–
	Private	–	–

APPENDIX 2: ENTITIES SUBJECT TO THE REGULATIONS

<i>Private sector (for-profit and not-for-profit)</i>
Pharmaceutical Wholesalers, distributors
Retail pharmacies
Pharmacies in private health facilities
<i>Public sector</i>
Rwanda Medical Supply Ltd.
Pharmacies in public health facilities such as Medicalized Health Centre, District Hospital, Specialized Hospital, Provincial Hospital, and Referral Hospital
Pharmacies in District hospitals
Pharmacies in Health centers
Pharmacies in Health Posts

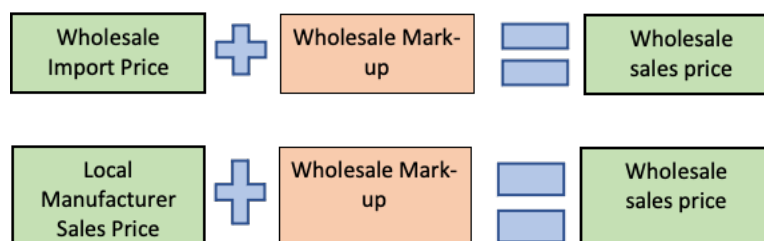
APPENDIX 3: THE DIFFERENT PRICES

Wholesaler Import price: the manufacturer's sales price increased with all relevant costs associated with international transport and with the costs associated with the import process and discounted for any discounts or rebates



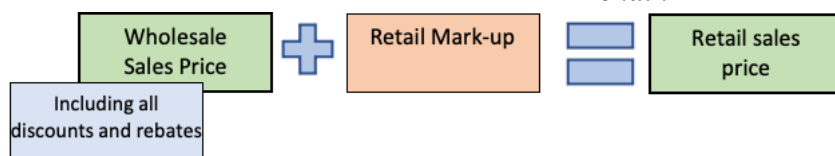
Delivery Duty Paid price: Equal to the Wholesaler Import Price

Wholesaler Sales Price: the addition of the Wholesaler Import Price and the wholesaler mark-up **or** the addition of the Local Manufacturer Sales Price and the wholesaler mark-up.



Retail Sales Price: price the retailer has paid to the wholesaler to obtain the product. It equals the Wholesaler Sales Price + the retail mark-up. Any purchase related costs (transport from wholesaler to retailer for example) are covered by the retail mark-up.

Guidelines for the implementation of mark-ups across the pharmaceutical supply and distribution chain



Human medicinal products sold by retail pharmacies and in health facilities

The Wholesaler Sale Price will include all general discounts or rebates.

The mark-up will be added to the Wholesaler Sales Price.



When a Human medicinal product is locally manufactured and the manufacturer also has a wholesaler license, the retailer can purchase directly from the manufacturer/wholesaler.

The wholesaler mark-up is included in the Manufacturer/Wholesaler sales price.



Local manufacturing: the calculation of the Wholesaler Sales Price

When a Human medicinal product is manufactured in Rwanda, the Wholesaler mark-up will be added to the Manufacturer Sales Price. The Manufacturer Sales Price will be discounted for all possible discounts and rebates.

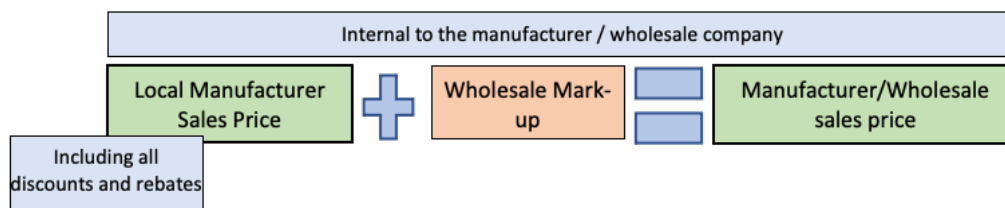


Manufacturer with a wholesaler license

It is possible that a manufacturer has a wholesaler license and sells to retailers and pharmacies. In that case, the wholesaler part of the company can include the maximum allowable mark-up to the manufacturer sales price.

In all cases, the company must be able to show that the wholesaler mark-up is equal to, or below, the maximum allowable wholesaler mark-up.

Guidelines for the implementation of mark-ups across the pharmaceutical supply and distribution chain



APPENDIX 4: LIST OF INFORMATION SOURCES

The list of information sources that will be used by the Authority.

Type of price	Source of information
Manufacturer price (EXW)	IRIMS/ Wholesaler records
Manufacturer price (local)	Manufacturer accounts, Wholesaler records, retailer records
Wholesaler import price	IRIMS / Wholesaler records
Wholesaler sales price	Wholesaler accounts, retailer accounts
Retail sales price	Retailer accounts, insurance companies
Private health facilities	HF accounts, insurance companies
Private Hospitals, Medicalized Health Centre, District Hospital, specialized Hospital, Provincial Hospital, Referral Hospital	Facility pharmacy accounts, Insurance companies
Health Centre	HC pharmacy, Insurance companies