



**REGULATIONS GOVERNING PROMOTION,  
ADVERTISEMENT AND MARKETING OF REGULATED  
PRODUCTS**

(Rwanda FDA law N° 003/2018 of 09/02/2018 Article 8)

Rwanda Food and Drugs Authority

## REGULATION DEVELOPMENT HISTORY

<b>DRAFT ZERO BY CONSULTANTS</b>	20 <sup>th</sup> May 2018
<b>ADOPTION BY RWANDA FDA</b>	18 <sup>th</sup> September 2020
<b>STAKEHOLDERS' CONSULTATION</b>	16 <sup>th</sup> October 2020
<b>ADOPTION OF STAKEHOLDERS' COMMENTS</b>	24 November 2020
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### Document Revision History

<b>Date of revision</b>	<b>Revision number</b>	<b>Changes made and/or reasons for revision</b>
18/06/2021	1	<ol style="list-style-type: none"><li>1. Provisions that require to sell, distribute or market regulated products by licensed or authorized personnel or establishment to authorized users;</li><li>2. Article and provisions on Marketing of Regulated products;</li><li>3. Provisions for administrative sanctions upon violation the regulations, sales, distributes, market and/or influence the inappropriate use of regulated products;</li><li>4. Provisions on marketing aspect of regulated products in different articles of the regulations;</li><li>5. The table revision history was included.</li></ol>

## **ADOPTION AND APPROVAL OF THE REGULATIONS**

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article 8 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations N° CBD/TRG/017 Governing the Promotion, Advertisement and Marketing of regulated products, made this 23<sup>rd</sup> day of July, 2021.

  
**Dr. Charles KARANGWA**  
Acting Director General



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**RWANDA FDA**

**Rwanda Food and Drugs Authority**

## CHAPTER I: GENERAL PROVISIONS

### Article One: Purpose of these regulations

The purpose of these regulations is to provide a legal framework for the effective and efficient control of the promotion and advertisement of regulated products and providing an open, transparent and non-discriminatory process for the application for approval of promotion, advertising and marketing of regulated products.

### Article 2: Citation

These regulations may be cited as “*Rwanda FDA Regulations Governing Promotion, Advertisement and Marketing of Regulated Products*”

### Article 3: Application

These regulations shall apply to all activities related to the advertisements or promotion and marketing of regulated products that are manufactured, imported, distributed, stored, sold or used in Rwanda.

### Article 4: Definitions

In these regulations, unless the context otherwise requires;

1. “**Advertisement**” means a form of communication through the media about products, services or ideas by an identified sponsor which is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action.
2. “**Advertising**” means anything that is aimed or designed to promote the supply, sale or use of a product whether or not for financial gain, and it includes but not limited to written communication materials (for instance a notice, circular, handouts, wrappers, catalogues, bill boards, posters, newspapers, magazines, digital and social media posters or other promotional document), oral and an audio materials (records, tapes, radio, ...) and visual announcement (films, video recordings, television, internet, electronic media, interactive data systems,...).
3. “**Appropriate fee**” means the fee prescribed in the Regulations N° CBD/TRG/004 related to regulatory service tariff/fees and fines.
4. “**Authority**” means Rwanda Food and Drugs Authority, Rwanda FDA.
5. “**Applicant**” means any advertisement agent, distributor, manufacturer or the sponsor of the advert.
6. “**General public**” means any person considered as a client or potential client.
7. “**Law**” means Law N°. 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning.

8. **“Marketing”** means to promote, distribute, sell, or advertise regulated products, or/and creating a relationship of the public and/or with information services regard to regulated products.
9. **“Media”** means newspaper, magazine, medical/journal, television, radio, the Internet; Out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital and social media, any form of projected light and sound recordings or any of such means of communication.
10. **“Misleading information”** means information that gives a wrong idea or impression
11. **“Promotion”** is any communication that attempts to influence people to buy or use the regulated products. It is the publicizing of a product so as to increase public awareness or sales using of audio-visual, oral or written material through advertising, sales promotion, direct marketing publicity, trade shows, promotional meetings, participation in exhibitions, giving samples, personal selling, etc.
12. **“Promotional material”** means any representation concerning the attributes of a product conveyed by any means whatsoever for the purpose of encouraging the usage of the product.
13. **“Regulated product”** means processed foods, pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs, food supplements, food fortificant, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products.
14. **“Pharmaceutical product”** 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 means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored, cleaning hospitals, and equipment and farm houses.



## **CHAPTER II: PROMOTION, ADVERTISEMENT AND MARKETING OF REGULATED PRODUCTS**

### **Article 5: Conditions for promoting, advertising and marketing of regulated products**

- (i) It is prohibited to advertise, promote or/and market any regulated products unless it is registered by the Authority.
- (ii) It is prohibited to advertise or promote any regulated product unless the advertisement or promotion has the clearance and approval issued by the Authority.
- (iii) It is prohibited to carry out regulated product launch unless a written prior approval or clearance by the Authority has been received.
- (iv) It is prohibited to promote, advertise or market a regulated product in a manner that is, directly or by implication, misleading or calculated to mislead the population.
- (v) All packaging and labelling materials shall provide information which is consistent with product information approved during the registration of the product.
- (vi) All promotional materials shall have a disclaimer owning all claims stated in the materials as well as disowning claims by third parties on any additional information regarding the product.
- (vii) It is prohibited to sell or distributed regulated products, create public product relationship or information services for non-authorized users.

### **Article 6: Content of promotional materials**

- (i) Promotional advertisements shall be accurate, unbiased, complete, clear and designed to promote credibility and trust by the general public and health care providers.
- (ii) Promotional advertisements shall be consistent with the approved product information. The promotion shall be in line with conditions or illnesses for which it has been registered.
- (iii) Promotional material shall not contain misleading or unverifiable statements or omissions regarding quality, safety and efficacy or value which likely induce product use or give rise to undue risks.
- (iv) A promotional aid (note pads, calendars and other such items) shall be limited to bear names of products currently registered in Rwanda.
- (v) Advertisements which unfairly undermine any product of a competitor, either directly or by implication are prohibited.
- (vi) Promotion shall not suggest either directly or by implication that one product is superior (or equivalent) to another identifiable treatment or product.
- (vii) Promotional advertisements for a product shall present information that is reasonably balanced between side effects and contra-indications and efficacy and safety. Promotions



should not state or imply that a product is “safe”, is “100% safe”, has “no side effects” or that its “use will not cause harm”.

- (viii) Promotional advertisements should not in any way discourage the public from seeking the advice of a healthcare provider.

### **Article 7: Prohibitions and restrictions**

- (i) It is restricted for every person to promote or advertise or carry out any promotional activities of regulated products, prior to obtaining written approval from the Authority;
- (ii) Promotion of regulated products to the public in open markets, bus stands and moving vehicles such as buses or any other public transport is not permitted unless approved by the Authority;
- (iii) The displaying of a poster for a specific regulated product in a public place, e.g. at hospitals, clinics, shops or anywhere shall be considered as promotional material targeting the general public and is therefore subject to approval by the Authority;
- (iv) An advertisement to the general public shall not refer to the provisions of this regulations, the Authority or any employee of the Authority;
- (v) Any language that brings or is likely to mislead or deceive or create fear or distress to individuals or community is prohibited;
- (vi) Any advertisement which uses words such as “Number one product”, “the best product” or any such words in promoting a product are hereby prohibited.
- (vii) Any product advertisement which may induce or attract children to use any regulated product is prohibited;
- (viii) Medicines and tobacco products shall not be promoted beyond determined circumstances;
- (ix) An advertisement shall not imply that if the reader, viewer or listener is suffering from any ailment or disease, he/she shall suffer more severely from the illness, ailment or disease on failure to use that particular drug product;
- (x) An advertisement shall not over-dramatize any symptoms by way of drawing a picture;
- (xi) An advertisement shall not denigrate or attack unfairly any competitive products;
- (xii) Breast Milk substitutes shall not be promoted and/or marketed beyond provisions of the Law regulating marketing of breast milk substitutes.

### **Article 8: False or misleading promotional advertisements**

- (i) No person shall promote, advertise or market any regulated product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, safety or efficacy as the case may be.
- (ii) Any promotional advertisement that imitates the general layout, text slogans, or visual presentation or devices of other advertisements from other companies in a way likely to mislead, deceive or confuse the consumer shall be considered false and misleading.

- (iii) Any promotional advertisement framed in such a manner as to exploit the belief system of and/or induce fear in the consumer to purchase the product shall be considered false and misleading;
- (iv) Any promotional advertisement that contains the words ‘magic’, ‘miracle’ or mystical’. Exotic descriptions such as ‘super potency’ or such other words as to induce daily and continuous use of the product shall be considered false and misleading;

#### **Article 9: Comparative promotion**

- (i) Comparison of regulated products for competition purposes is prohibited.
- (ii) Promotion or advertisement that unfairly criticise any company of its competitive products either directly, indirectly or by implication are be prohibited.
- (iii) Comparison of new version of the same products shall be factual, fair, reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way;
- (iv) For promotion of drugs, only molecules can be compared but not brands.
- (v) Hinging comparatives; those which merely claim that a product is better, stronger, more widely prescribed is prohibited

#### **Article 10: Application for promotion or advertisement of regulated products**

An application to promote or advertise a regulated product shall be prepared in accordance with requirements as provided in the relevant guidelines on promotion and advertisement of regulated products.

#### **Article 11: Approval for promotion or advertisement of regulated products**

- (i) The final version of the advertisement in whatsoever form shall be submitted for vetting before final publication;
- (ii) Advertisements considered acceptable by the Authority will be communicated in writing to the applicant with a clear indication of the unique reference number for each advertisement, issued by the Authority;
- (iii) Advertisements considered unacceptable by the Authority will be communicated in writing to the applicant with clear clarification on the unacceptable information or illustration and on the ruling thereof;
- (iv) Any alterations in the format of the approved advertisement without express written permission of the Authority will render the approval null and void and shall attract fines as provided for in the Regulations related to regulatory service tariff/fees and fines currently enforced;
- (v) Notwithstanding the above, the Authority reserves the right to revoke approval of an advertisement as the result of new evidence concerning product or public safety or product efficacy or quality.

### **Article 12: Validity of approval**

The duration of approval of an advertisement shall be two (2) years for drugs and high risk foods and five (5) years for other products.

### **Article 13: Withdrawal of approval**

The Authority shall withdraw the approval for an advertisement or promotion if:

- (i) the grounds on which the approval was granted was later found to be false or incomplete;
- (ii) any of the conditions under which the approval was granted has been contravened, or;
- (iii) in the light of new scientific evidence against claims contained in the advertisement.

### **Article 14: Regulation of Medical Representative for regulated products**

- (i) Any person, prior to exercising as medical representative of regulated product, shall have an authorization issued by the Authority;
- (ii) The medical representative shall possess minimum qualification of A1 in medical science (Pharmaceutical, Medicine and Surgery, Veterinary medicine, Nursing and Midwife, Dental therapy/Surgery, Clinical medicine, Anaesthesia, Ophthalmology, Laboratory, Bio-Medical Engineering, Clinical psychology, Public health) or life sciences (Bio-Technology, Biology, Chemistry, Microbiology...) from recognized institution with relevant experience and/or trainings in matters related to medicines.
- (iii) The requirements for registration of medical representative shall be detailed in relevant guidelines.
- (iv) During promotion, advertisement or marketing of regulated product, the medical representatives shall fulfil their basic function as opportunities to provide unbiased scientific information to prescribers and dispensers.

### **Article 15: Importation of promotional materials**

- (i) Any person who imports promotional samples shall also comply to regulations.
- (ii) Importation of promotional materials require an import licence. However, it is not subject to importation fee.
- (iii) The importer may apply for approval of promotional materials before importing them by submitting the mock-up or design to the Authority for review.



**Article 16: Promotion and advertisement authorization timelines**

The review process of promotion and advertisement application by the Authority shall not exceed 10 working days upon compliance with all requirements.

**Article 17: Marketing of Regulated products**

- (i) Regulated products shall be marketed by authorized personnel and at authorized establishments.
- (ii) Medicines, breast-milk substitute, and food supplement products shall be dispensed up on prescription of qualified medical doctor or other healthcare professionals licensed to do so. Exception to this should be backed up with other regulations and guidelines.
- (iii) It is prohibited to sale or distribute regulated products to unauthorized user.
- (iv) It is prohibited to deploy marketing strategies such us pyramid schemes, setting quotas, providing incentives or bonus in accordance to the quantity of sales and others that influence increased use of a particular regulated product in a specifically targeted population group or general public.
- (v) It is prohibited for medical doctors, pharmacists or other healthcare professionals to promote or influence excessive or inappropriate use of a certain regulated product for the sake of financial gains or driven by other personal of interests.
- (i) Any person who sales, distribute or market regulated products in the manners that contradict with provisions of this regulations shall be sanctioned with Administrative fines as prescribed in the Authority Regulations N° CBD/TRG/004 related to regulatory service tariff/fees and fines.

### **CHAPTER III: MISCELLANEOUS PROVISIONS**

#### **Article 18: Power to issue guidelines on promotion, advertisement and marketing**

The Authority shall issue guidelines, Standards Operating procedures (SOPs), forms necessary for the implementation of these regulations.

#### **Article 19: Languages**

All promotion and advertisement application and supporting documents shall be presented in at least one of the official language used in Rwanda.

#### **Article 20: Administrative Sanctions**

Any person who contravenes any of the provisions of these regulations shall be guilty of an offence under these Regulations and shall be liable to any of the administrative sanctions and penalties as stipulated in the regulations related to regulatory service tariff/ fees and fines issued by the Authority.

- (ii) Upon violation of these Regulations, any person who advertises regulated products will be sanctioned with a written warning on the first time of the violation.
- (iii) A person who violates any of the provisions of these regulations for the second time or alters the previously approved promotional material shall be sanctioned with Administrative fines as prescribed in the Authority Regulations N° CBD/TRG/004 related to regulatory service tariff/fees and fines.
- (iv) Any person who displays a promotional material in any form that was not previously approved by the Authority shall be sanctioned with administrative fine.
- (v) Any person who violated the Regulations, sales, distributes, market and/or influence the used of regulated products in manners that are different to provisions of regulation shall be sanctioned administratively as prescribed in the Authority Regulations N° CBD/TRG/004 related to regulatory service tariff/fees and fines.
- (vi) Repeated offense shall lead to de-registration of the product.

#### **Article 21: Appeals to the authority**

Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) working days from the date of notice.

The Authority shall, within fifteen (15) working days from the date of receiving the application, review, reject or vary its own decision.

However, if after reconsideration of the application, the Authority still rejects the application, the applicant shall appeal to the Board of Directors.

**Article 22: Commencement**

This regulation shall enter into force on date of its signature and publication. All prior contrary provisions to these regulations are hereby repealed.

**End of Document**

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