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Rwanda Food and Drugs Authority

REGULATIONS GOVERNING PROMOTION AND ADVERTISEMENT OF REGULATED PRODUCTS

(Rwanda FDA law N^{o} 003/2018 of 09/02/2018 Article 8)

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REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY CONSULTANTS	20th May 2018
ADOPTION BY RWANDA FDA	18th September 2020
STAKEHOLDERS' CONSULTATION	16th October 2020
ADOPTION OF STAKEHOLDERS' COMMENTS	24 November 2020
DATE FOR COMING INTO EFFECT	31st December 2020

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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 and Advertisement of regulated products, made this 31st December 2020.

Dr. Charles KARANGWA
Ag. Director General

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CHARPTER 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 and advertising of regulated products.

Article 2: Citation

These regulations may be cited as *"Rwanda FDA Regulations Governing Promotion and Advertisement of Regulated Products"*

Article 3: Application

These regulations shall apply to all activities related to the advertisements or promotion 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^{o} 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^{o}. 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning.
8. **"Misleading information"** means information that gives a wrong idea or impression

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. **"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.
11. **"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.
12. **"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.
13. **"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.

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CHAPTER II: PROMOTION AND ADVERTISMENT OF REGULATED PRODUCTS

Article 5: Conditions for promoting and advertising regulated products

(i) It is prohibited to advertise or promote 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 or advertise 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.

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.

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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 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 beyond provisions of the Law regulating marketing of breast milk substitutes.

Article 8: False or misleading promotional advertisements

(i) No person shall promote or advertise 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;

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(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.

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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 or advertisement 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.

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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.

CHAPTER III: MISCELLANEOUS PROVISIONS

Article 17: Power to issue guidelines on promotion and advertisement

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

Article 18: Languages

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

Article 19: 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.

(i) 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.
(ii) 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^{o} CBD/TRG/004 related to regulatory service tariff/fees and fines.
(iii) Any person who displays a promotional material in any form that was not previously approved by the Authority shall be sanctioned with administrative fine.
(iv) Repeated offense shall lead to de-registration of the product.

Article 20: 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 21: 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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