Rwanda

Law establishing Rwanda Food and Drugs Authority and Determining its Mission, Organisation and Functioning

Law 3 of 2018

Legislation as at 27 February 2018

FRBR URI: /akn/rw/act/law/2018/3/eng@2018-02-27

About this collection

The legislation in this collection has been reproduced as it was originally printed in the Government Gazette, with improved formatting and with minor typographical errors corrected. All amendments have been applied directly to the text and annotated. A scan of the original gazette of each piece of legislation (including amendments) is available for reference.

Law establishing Rwanda Food and Drugs Authority and Determining its Mission, Organisation and Functioning

Contents

Rwanda

Law establishing Rwanda Food and Drugs Authority and Determining its Mission, Organisation and Functioning

Law 3 of 2018

Published in Official Gazette special on 27 February 2018

Assented to on 9 February 2018

Commenced on 27 February 2018

[This is the version of this document from 27 February 2018.]

We, KAGAME Paul,

President of the Republic;

THE PARLIAMENT HAS ADOPTED AND WE SANCTION, PROMULGATE THE FOLLOWING LAW AND ORDER IT BE PUBLISHED IN THE OFFICIAL *GAZETTE* OF THE REPUBLIC OF RWANDA

THE PARLIAMENT:

The Chamber of Deputies, in its session of 28 December 2017;

Pursuant to the Constitution of the Republic of Rwanda of 2003 revised in 2015, especially in Articles 64, 69, 70, 88, 90, 91, 106, 112, 119, 120, 139, 165 and 176;

Pursuant to Organic Law n° 001/2016/OL of 20/04/2016 establishing general provisions governing public institutions;

Having reviewed Law n° 74/2013 of 11/09/2013 establishing Rwanda Food and Medicines Authority and determining its mission, organization and functioning;

ADOPTS:

Chapter One
General provisions

Article One – Purpose of this Law

This Law establishes Rwanda Food and Drugs Authority and determines its mission, organization and functioning.

Article 2 – Establishment of Rwanda FDA

There is established Rwanda Food and Drugs Authority, abbreviated as "Rwanda FDA".

Article 3 – Scope of this Law

This Law regulates the following:

1° human and veterinary drugs;

2° human and animal vaccines and other biological products used in clinical as drugs;

3° processed food for humans and animals, food supplements and fortified foods;

4° poisonous substances;

5° herbal medicines;

6° medicated cosmetics;

7° human and veterinary medical devices;

8° tobacco and tobacco products;

9° management of unfit pharmaceutical products;

10° clinical trials on pharmaceutical products for human and veterinary use;

11° drugs' post marketing surveillance and safety monitoring;

12° compliance with quality standards for the manufacture, export, storage, sale, distribution, use and export of products regulated by this Law;

13° premises used in the manufacture of products regulated by this Law;

14° labels, packages and raw materials used in the manufacture of products regulated by this Law;

15° laboratory and cleaning chemicals and pesticides.

Article 4 – Definitions of terms

For the purpose of this Law, the following terms have the following meanings:

1° medical device: any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection;

2° food products: any animal or plant products that have been processed or transformed from their original state and are intended for human or animal consumption with the exception of pharmaceutical products, tobacco, food additives and food fortificants;

3° food fortificant: a substance, in a chemical or a natural form, added to food to increase its nutritive value;

4° clinical trial: any systematic study on pharmaceutical products, human or animal medical devices, food products, food supplements, cosmetics, human and animals vaccines and other biological products used in clinical as drugs in order to discover or verify the efficacy or the effects of use thereof;

5° animal: any animal raised for any interest whatsoever, whether it is a domestic animal or it is a wild animal kept in captivity;

6° marketing authorization: a legal document issued by the competent authority for the purposes of marketing or free distribution of a product which has been approved after evaluation for safety, efficacy and quality;

7° pharmaceutical product: 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, equipment and farm houses.

Article 5 – Legal personality and autonomy

Rwanda FDA has legal personality and enjoys administrative and financial autonomy and is managed in accordance with relevant laws.

Article 6 – Category of Rwanda FDA

Rwanda FDA falls within the category of non-commercial public institutions.

Article 7 – Head office of Rwanda FDA

The head office of Rwanda FDA is located in the City of Kigali, the Capital of the Republic of Rwanda. It may be relocated elsewhere on the Rwandan territory when deemed necessary, upon approval by a Prime Minister's Order.

Rwanda FDA may have branches elsewhere in the country when deemed necessary in order to fulfil its mission, upon approval by a Prime Minister's Order.

Chapter II
Missions and powers of Rwanda FDA

Article 8 – Missions of Rwanda FDA

Missions of Rwanda FDA are the following:

1° regulate pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs food supplements, food fortificants fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical and food products and clinical trials on pharmaceutical products for human and veterinary use;

2° regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this Law;

3° regulate laboratory and cleaning chemicals and pesticides as well as premises involved in the manufacture of products regulated under this Law;

4° establish, approve and publish the list of human and veterinary food and pharmaceutical products as well as other products regulated under this Law for which marketing authorization has been granted;

5° establish and publish the list of prohibited cosmetics;

6° establish the quality assurance and quality control of products regulated under this Law through designated quality control laboratories when necessary;

7° to regulate and inspect clinical trials;

8° ensure that processed food, food supplements and fortified food meet the prescribed quality standards before they are placed on the market;

9° conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated under this Law;

10° follow up and analyse information on the use of pharmaceutical products that are subject to global drugs safety monitoring;

11° regulate and analyse information used in the promotion, advertising and marketing of products regulated under this Law;

12° regulate the use of unregistered products regulated under this Law for clinical trial purposes or compassionate use;

13° disseminate information on quality and safety of products regulated under this Law to health professionals and to other concerned persons;

14° conduct research and studies on food and pharmaceutical products and publish the findings in order to promote investment;

15° build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions;

16° to advise the Government on matters regarding the products regulated under this Law;

Article 9 – Powers of Rwanda FDA

Powers of Rwanda FDA are as follows:

1° formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products under this Law;

2° grant or withdraw authorization relating to matters regulated under this Law;

3° seize and confiscate any product regulated under this Law not conforming to the provisions of this Law;

4° establish tariff for services rendered by Rwanda FDA;

5° impose administrative sanctions arising from breach of the provisions of this Law;

Chapter III
Supervising authority of Rwanda FDA and performance contract

Article 10 – Supervising authority of Rwanda FDA

The supervising authority of Rwanda FDA is determined by a Prime Minister's Order.

Article 11 – Performance contract

Rwanda FDA operates on the basis of performance contract.

Modalities for the conclusion and evaluation of performance contract of Rwanda FDA are determined by relevant laws.

Chapter IV
Organisation and functioning of Rwanda FDA

Article 12 – Management organs of Rwanda FDA

The management organs of Rwanda FDA are the following:

1° the Board of Directors;

2° the Executive Organ.

Section One – Board of Directors of Rwanda FDA

Article 13 – Composition of the Board of Directors of Rwanda FDA

The Board of Directors of Rwanda FDA is composed of seven (7) members appointed by a Presidential Order including the Chairperson and the Deputy Chairperson.

Members of the Board of Directors are selected on the basis of their competence and expertise.

At least thirty percent (30%) of the members of the Board of Directors shall be females.

The term of office of the members of the Board of Directors as well as their replacement are determined by a Presidential Order.

Article 14 – Powers of the Board of Directors

The Board of Directors of Rwanda FDA is the supreme management and decision making organ. It has full powers to make decisions regarding administration, human resources and property of Rwanda FDA in order to fulfil its mission.

Article 15 – Responsibilities of the Board of Directors

The responsibilities of the Board of Directors of Rwanda FDA are the following:

1° to oversee the functioning of the Executive Organ and provide strategic guidance to be followed in the fulfilment of its mission;

2° to approve strategic plan and action plan of Rwanda FDA and related reports;

3° to sign a performance contract with the supervising authority of Rwanda FDA and follow up its implementation;

4° to approve the procedures manual and internal rules and regulations of Rwanda FDA;

5° to approve the draft budget proposal of Rwanda FDA and monitor the budget use and its execution;

6° to take decision on all matters falling under the mission of Rwanda FDA;

7° to assess the functioning of Rwanda FDA in accordance with the action plan and budget;

8° to adopt the draft organizational structure of Rwanda FDA;

9° to adopt activity and financial reports for the previous year;

10° to submit a quarterly report to the supervising authority of Rwanda FDA.

Article 16 – Duties of the Chairperson of the Board of Directors

The Chairperson of the Board of Directors of Rwanda FDA has the following duties:

1° to head the Board of Directors and coordinate its activities;

2° to convene and preside over meetings of the Board of Directors;

3° to submit resolutions and a copy of the minutes of the meetings of the Board of Directors of Rwanda FDA to its supervising authority;

4° to sign the performance contract between the Board of Directors and the supervising authority of Rwanda FDA;

5° to submit Rwanda FDA reports adopted by the Board of Directors to relevant organs;

6° to follow up the implementation of resolutions of the Board of Directors;

7° to perform any other duties falling within the mission of the Board of Directors as may be assigned to him/her by the Board of Directors.

Article 17 – Duties of the Deputy Chairperson of the Board of Directors of Rwanda FDA

The Deputy Chairperson of the Board of Directors has the following duties:

1° to assist the Chairperson and replace him/her in case of absence;

2° to perform any other duties falling within the mission of the Board of Directors as may be assigned to him/her by the Board of Directors.

Article 18 – Incompatibilities with membership of the Board of Directors of Rwanda FDA

Members of the Board of Directors are not allowed to perform any remunerated activity within Rwanda FDA.

Members of the Board of Directors are also not allowed, neither individually nor through companies in which they hold shares, to bid for tenders of Rwanda FDA.

Article 19 – Reasons for loss of membership to the Board of Directors and modalities for replacement

A member of the Board of Directors of Rwanda FDA loses membership if:

1° his/her term of office expires;

2° he/she resigns in writing;

3° he/she is no longer able to perform his/her duties due to the physical or mental disability certified by a committee of three (3) recognized medical doctors;

4° he/she is definitively sentenced to a term of imprisonment equal to or exceeding six (6) months;

5° he/she is absent in meetings for three (3) consecutive times without valid reasons;

6° he/she manifests any behaviour likely to compromise his/her dignity, that of his/her work or his/her position;

7° he/she jeopardizes the interests of Rwanda FDA;

8° he/she is convicted of the crime of genocide or genocide ideology;

9° he/she no longer fulfils the requirements considered at the time of his/her appointment;

10° he/she dies.

In case a member of the Board of Directors of Rwanda FDA leaves his/her duties before the expiration of his/her term of office, the competent authority appoints his/her substitute to complete his/her predecessor's term of office.

Article 20 – Convening and holding of meeting of the Board of Directors of Rwanda FDA and modalities for decision-making

The meeting of the Board of Directors of Rwanda FDA is held once a quarter and whenever necessary upon invitation by its Chairperson or Deputy Chairperson in case of absence of its Chairperson, at their own initiative or upon a written request by at least a third (1/3) of its members.

The invitation is submitted in writing to the members of the Board of Directors at least fifteen (15) days before the meeting is held.

However, an extraordinary meeting is convened in writing in a period not exceeding three (3) days before the meeting is held.

Items to be considered by the Board of Directors in the first quarter of the year include the approval of the financial and activity reports of the previous year.

In every quarter, the Board of Directors must examine the financial and activity reports relating to the previous quarter to be submitted to the supervising authority of Rwanda FDA.

The quorum for a meeting of the Board of Directors is two-thirds (2/3) of its members.

However, when a meeting is convened for the second time it takes place regardless of the number of its members present.

The Director General of Rwanda FDA attends the meetings of the Board of Directors.

Modalities for decision-making by the Board of Directors of Rwanda FDA are determined by internal rules and regulations of Rwanda FDA.

Article 21 – Invitation of a resource person to the meeting of the Board of Directors

The Board of Directors of Rwanda FDA may invite in its meeting any person from whom it may seek advice on a certain item on the agenda.

The invited person is neither allowed to vote nor to follow debates on other items on the agenda.

Article 22 – Approval of resolutions and minutes of the meeting of the Board of Directors

Resolutions of the meeting of the Board of Directors are signed by its members immediately after the end of the meeting and their copy is sent to the supervising authority of Rwanda FDA in a period not exceeding five (5) working days.

The head of the supervising authority of Rwanda FDA gives his/her views on the resolutions of the meeting of the Board of Directors in a period not exceeding fifteen (15) working days from their receipt. If this period expires before he/she gives his/her views, the resolutions of the meeting are considered definitively approved.

The minutes of the meeting of the Board of Directors are signed by the Chairperson and its rapporteur and approved during the next meeting. A copy of minutes of the meeting is sent to the supervising authority of Rwanda FDA in a period not exceeding fifteen (15) working days from the date of its approval.

Article 23 – Rapporteur of the meeting of the Board of Directors

The Director General of Rwanda FDA serves as the rapporteur of the meeting of the Board of Directors, but he/she has no right to vote in decision making.

The Director General of Rwanda FDA does not participate in the meetings that make decisions on issues that concern him/her personally.

In that case, members of the Board of Directors elect among themselves a rapporteur.

Article 24 – Personal interest in issues on the agenda

When a member of the Board of Directors has a direct or indirect interest in the issue to be considered, he/she must immediately inform the Board of Directors about where his/her interest lies. The member who declares his/her interest in the issue to be considered cannot attend the meeting deliberating on that issue.

When it happens that many or all members of the Board of Directors have a direct or indirect interest in the issues to be considered in such a way that it is impossible to take a decision on the issue, the issue is submitted to Rwanda FDA supervising authority which decides thereon within thirty (30) days.

Article 25 – Sitting allowances for members of the Board of Directors

A Presidential Order determines the sitting allowances for members of the Board of Directors.

Section 2 – Executive Organ

Article 26 – Composition of the Executive Organ of Rwanda FDA

The Executive Organ of Rwanda FDA is composed of the Director General appointed by a Presidential Order and other staff members recruited in accordance with relevant laws.

A Presidential Order may also appoint Deputy Directors General and determine their powers and duties.

Article 27 – Responsibilities of the Executive Organ

The Executive Organ of Rwanda FDA has the following key responsibilities:

1° to monitor and coordinate daily duties and activities;

2° to perform any other duty as may be assigned by the Board of Directors falling within the mission of Rwanda FDA.

Article 28 – Powers and duties of the Director General of Rwanda FDA

The Director General of Rwanda FDA has the power of decision in the administrative and financial management of Rwanda FDA in accordance with relevant laws. He/she coordinates and directs the activities of Rwanda FDA.

The Director General of Rwanda FDA has the following duties:

1° to serve as legal representative of Rwanda FDA;

2° to monitor daily activities of Rwanda FDA;

3° to serve as the spokesperson of Rwanda FDA;

4° to ensure the implementation of the decisions of the Board of Directors of Rwanda FDA;

5° to ensure the management of staff, equipment and property of Rwanda FDA and submit a related report to the Board of Directors;

6° to prepare the activity plan and report to be approved by the Board of Directors of Rwanda FDA;

7° to prepare the draft internal rules and regulations of Rwanda FDA to be approved by the Board of Directors of Rwanda FDA;

8° to prepare and implement the strategic plan and action plan of Rwanda FDA;

9° to prepare the draft budget proposal of Rwanda FDA;

10° to ensure the execution of Rwanda FDA budget;

11° to produce the annual activity and financial reports of Rwanda FDA;

12° to perform such other duty relating to the mission of Rwanda FDA as the Board of Directors may assign to him/her.

Article 29 – Statutes governing the staff of Rwanda FDA

The staff of Rwanda FDA is governed by a special statute determined by a Presidential Order.

Article 30 – Salaries and other fringe benefits allocated to members of the Executive Organ

The salaries and other fringe benefits allocated to members of the Executive Organ of Rwanda FDA are determined by the special statute governing Rwanda FDA staff.

Article 31 – Organization and functioning of organs of Rwanda FDA

The organization and functioning of organs of Rwanda FDA are determined by the special statute governing Rwanda FDA staff.

Chapter V
Property and finance of Rwanda FDA

Article 32 – Property of Rwanda FDA and its sources

The property of Rwanda FDA is comprised of movable and immovable assets.

The property of Rwanda FDA derives from the following sources:

1° State budget allocations;

2° State or development partners' subsidies;

3° income from services rendered;

4° interests from its property;

5° loans granted to Rwanda FDA as approved by the Minister in charge of finance;

6° donations and bequests.

Article 33 – Budget of Rwanda FDA

Rwanda FDA prepares its annual budget to be approved by the competent authority and executed in accordance with relevant laws.

Article 34 – Use, management and audit of property of Rwanda FDA

The use, management and audit of the property of Rwanda FDA are carried out in accordance with relevant laws.

The internal audit service of Rwanda FDA submits a report to the Board of Directors and provide a copy to its Director General.

Article 35 – Annual financial report

Within three (3) months following the end of the financial year, the Director General of Rwanda FDA submits to the supervising authority of Rwanda FDA the annual financial report after its approval by the Board of Directors in accordance with laws governing the management of State finance and property.

Chapter VI
Final provisions

Article 36 – Drafting, consideration and adoption of this Law

This Law was drafted in English, considered and adopted in Ikinyarwanda.

Article 37 – Repealing provision

Law n° 74/2013 of 11/09/2013 establishing Rwanda Food and Medicines Authority and determining its mission, organization and functioning and all prior legal provisions contrary to this Law are repealed.

Article 38 – Commencement

This Law comes into force on the date of its publication in the Official *Gazette* of the Republic of Rwanda.

