

MINISTERIAL DECREE N° 20/15 OF 03/05/2005 DETERMINING CONDITIONS OF ESTABLISHING MODALITIES FOR RUNNING AND TRANSFERRING A RETAIL PHARMACY OR A PHARMACEUTICAL STORE

The Minister of Health,

Given the Constitution of June 4,2003, as revised to date especially in its Articles 120(1), 121(1) and 201 ;

Given of the Law n° 12/99 of 02/07/1999 of the pharmaceutical art, particularly in its articles 8, 12 and 102(2) ;

After consideration and approval by Cabinet meeting in its session of 26 January 2005,

DECREED :

CHAPTER I: GENERAL DISPOSITIONS

Article One:

Retailing pharmacy means the establishment which mainly deals with dispensing, preparing preserving and controlling the quality of drugs and other pharmaceutical products.

Article 2:

Pharmaceutical store means all premises where pharmaceutical activities are limited to the conservation and retail distribution of certain drugs and other pharmaceutical products whose list is determined by the Minister having health in his attributions.

CHAPTER II: CONDITIONS OF ESTABLISHMENT

Article 3:

Opening up or transferring either a retail pharmacy or a pharmaceutical store, requires the concerned to lodge, first and foremost, an application with all the pre-requisites attached therein, to the office of the minister having health in his attributions who determines the approval of the said application but having had consulted and approved by the National Committee for pharmaceutical establishment implementation.

Article 4 :

The application file must contain :

- 1° An application letter requesting approval, the letter must bear the signature of the proprietor, or that of the person officially representing a given pharmaceutical institution, or one with power to sign on behalf of the institution. The letter must be approved by the respective head of the Province or Mayor of Kigali City;
- 2° A detailed curriculum vitae of the pharmacist in-charge or of the responsible of the pharmaceutical store;
- 3° A legally certified copy of certificates of the pharmacist in-charge, ones that conform to the original;
- 4° A fully completed application form obtainable from the Ministry with health in its attributions;
- 5° A receipt certifying payment of such a fee fixed by the Minister having finance in his attributions.

Article 5:

For pharmacies not opened to public (services for the distribution of the pharmaceutical products either in old public health institutions, or in any other approved health institutions, or private ones, or in public or private firms), the application file mentioned in the previous article must contain a written undertaking made by a person legally authorised to represent a given institution, stating there-in, that he/she will provide drugs only to patients for their treatment in his/her respective pharmacy.

Article 6:

Based on the fact that a pharmacist is employed by another person ; official request to set-up a pharmacy must be accompanied by a contract ascertaining collaboration, one entitled "Partnership contract", jointly signed by the pharmacist in-charge, and the official representative of the pharmaceutical institution in question.

Article 7:

Any false declaration impedes the reply to the submitted application and if need-be, hand the file the legal authorities.

Article 8:

The date on which a complete application file is received in the Ministry having health in its attributions, shall determine the filing order of the received applications.

A prioritised order on granting approval is based on the following:

1° Application for opening a pharmacy is given priority over application for opening a pharmaceutical store in the same location;

2° The first applicant for the same type of pharmaceutical institution, whose application was received by a stamp of acknowledgement from the Ministry having health in its attributions.

Article 9:

The beholder who fails to make use of the granted approval within a period of six months shall be deprived of it.

Article 10:

A prior inspection shall be carried-out by the respective department in the Ministry having health in its attributions, before setting-up a retail pharmacy or a pharmaceutical store.

Within fifteen working days, the department of inspection shall have informed the applicant of the decision held.

**CHAPTER III : CONDITIONS AND MODALITIES FOR EXPLOITATION OF A
PHARMACY AND PHARMACEUTICAL STORE**

Section I : Technical conditions of operation

Article 11 :

All retail pharmacies and pharmaceutical stores must be kept in good working conditions which ensure quality products.

The preparation, assessment, cross examination, packaging, storage as well as the distribution of drugs and other pharmaceutical products must be handled by a person free from contagious diseases.

Article 12 :

Premises must be kept satisfactorily clean and should be used only for pharmaceutical purposes.

The storage materials for drugs and other pharmaceutical products must be quite different from other premises, where chemical products are either stored or handled. Such chemical products must be preserved in respect to specific international norms.

Article 13 :

Necessary measures must be taken not to expose the staff of a pharmaceutical institute to risks accrued from either pharmaceutical products, or dangerous or toxic substances.

Article 14 :

The general rules in matters of hygiene and security at work premises are equally applicable in retail pharmacies as well as pharmaceutical stores.

Section II : Replacement, hand-over, resumption and transfer

Article 15 :

A retail pharmacy or a pharmaceutical store can not be left open in the absence of the pharmacist in-charge; and that the out-going pharmacist must be replaced by another pharmacist approved by the Ministry with health in its attributions.

The out-going pharmacist in-charge must acknowledge of his departure to the Ministry having health in its attributions and a letter of acknowledgement must be accompanied with a written undertaking by the in-coming pharmacist confirming effective replacement of the former.

Article 16:

In case the owner of a retail pharmacy or a pharmaceutical store dies, inheritance can be allowed by the Ministry with health in its attributions to operate for at least a period of about 12 months right from the date of the owners' death.

After this period, the pharmacy must either be disposed of or closed.

Article 17 :

A resumption or hand-over of a retail pharmacy or a pharmaceutical store depends on the approval of the Ministry having health in its attributions, based on the rules stipulated in article 6 of the Law n° 12/99 governing the pharmaceutical art.

The approval of a retail pharmacy or hand-over of a pharmaceutical store is wholly repealed

Article 18 :

The transfer of a retail pharmacy or a pharmaceutical store can only be approved when such a transfer does not jeopardise the normal supplies' level of the population living where such an institution has been originally established.

Article 19 :

A provisional transfer can be granted by the Minister having health in his attributions but for a period of one month, with bid to allow the realisation of some work meant for the improvement of a given retail pharmacy or a pharmaceutical store. Such a transfer can not exceed 150 metres and can only be renewed once.

Any transfer of retail pharmacy or a pharmaceutical store has to depend on the approval given by the Ministry having health in its attributions but having been duly advised by the National Committee for pharmaceutical establishment implementation.

Article 20 :

An application file for a transfer must include : an application letter, a written proof justifying the reasons for such a requested transfer and lastly, a photocopy of the official authorisation which allows the pharmaceutical firm in question to operate.

Article 21 :

Any retail pharmacy or pharmaceutical store handed-over cannot be relocated from its original location without conforming to the provisions of the present decree.

CHAPTER IV : FINAL PROVISIONS

Article 22 :

All previous provisions contrary to this decree are repealed.

Article 23 :

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

Done at Kigali, on 3rd May 2005

The Minister of Health,
Dr NTAWUKULIRYAYO Jean Damascène
(sé)

Seen and sealed with the Seal of the Republic:

The Minister of Justice
MUKABAGWIZA Edda
(sé)