

MINISTERIAL DECREE N° 20/12 OF 03/05/2005 DETERMINING THE CONDITIONS FOR OPENING AND OPERATING OF WHOLESALE 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 the law n° 12/99 of 02/07/1999 related to pharmaceutical art, especially in its articles 8, 12 and 28;

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

DECREES:

CHAPTER ONE: GENERAL DISPOSITIONS

Article one:

Wholesale pharmaceutical establishments means any establishment whose aim and activity is storage, distribution and wholesale as well as import or export of pharmaceutical products.

CHAPTER II : MODE OF ESTABLISHMENT

Article 2 :

In order for any whole-sale pharmaceutical institution to start its operations, it is required to submit a complete application file to the Ministry with health in its attributions, which decides as to whether, the pharmaceutical institution applying for a work permit is worth. However, the permit is normally granted upon the recommendation of the National Committee for pharmaceutical implementation.

Article 3:

The application file ought to possess the following:

- 1° A letter applying for a permit and signed by the owner of the institution or any other person legally acceptable to act on behalf of the institution;
- 2° Certified copies of the certificates pharmacist in-charge by the notary of the Republic, conforming to the originals ;
- 3° A certificate of registration to the council of pharmacists;
- 4° A dully filled application form for a work permit, obtainable for the Ministry with health in its attribution; and
- 5° A detailed curriculum vitae of the pharmacist in-charge,
- 6° A receipt proving payment of such amount as determined by the Minister having finance in his attributions.

Article 4 :

The application file must be accompanied by a "Partnership contract" jointly signed by the pharmacist and the person legally authorised to act on behalf of the institution stating that a pharmacist of a wholesale pharmaceutical institution must be entrusted with the powers to carryout, quite rightly, his/her assignments.

Article 5 :

Any false declaration retards any possible feed-back to the application made, and if need be, forward it to the judicial authorities.

CHAPTER III : CONDITIONS AND MODES OF OPERATIONS

Section I : General rules

Article 6 :

Any person working in a whole-sale pharmaceutical institution must be free of contagious diseases.

Article 7 :

The general rules pertaining to hygiene and security and around work premises equally applies to the whole-sale pharmaceutical institutions.

Necessary measures should be taken not to expose the staff of a pharmaceutical institution to health hazards accrued from either handling chemical products, dangerous or toxic substances.

Section II : Replacement, hand-over and resumption

Article 8 :

A whole-sale pharmaceutical institution cannot be opened in the absence of the pharmacist in-charge, and that the out-going pharmacist in-charge should equally be replaced by another, approved by the Ministry with health in its attributions.

The out-going pharmacist ought to acknowledge his absence to the Ministry with health in its attributions. Also attached to this written acknowledgement should be a written undertaking committing the in-coming pharmacist to effective replacement.

Article 9 :

Resumption or hand-over of a whole-sale pharmaceutical institution must be approved by the Ministry with health in its attributions there-by abiding by the governing rules as clearly stipulated in article 29 of the Law n° 12/99 related to pharmaceutical art.

Section III : Importation and Distribution of Pharmaceutical Products

Article 10 :

All imports of drugs or any other pharmaceutical products requires prior of the Ministry with health in its attributions.

The effective entry of drugs and other pharmaceutical products into the national territory, is possible upon the presentation of an import licence obtainable from the Ministry having health in its attributions and a certificate from the quality control of pharmaceutical products obtainable from a manufacturing industry and testified by the legally approved authorities of the exporting country.

Article 11 :

Whole-sale pharmaceutical institutions should only distribute pharmaceutical products to :

- 1° Licensed pharmaceutical firms by the Ministry having health in its attributions ;
- 2° Authorised pharmaceutical stores established in respect to the existing law;
- 3° Public health institutions, or those that are State subsidised, or health insurance associations, or other non-profit making social groups approved by the Ministry having health in its attributions ;
- 4° Approved private health institutions that respect the existing rules and regulations.

Article 12 :

For both generic drug or pharmaceutical speciality, the label and leaflet should be written in any one of the official languages used in Rwanda.

Article 13 :

All the packaging pharmaceutical must, additionally, bear the following guiding information on the original label stuck thereon:

- 1° Name and address of the packaging firm;
- 2° The pharmaceutical form and the number of pieces contained thereof;
- 3° Packaging and expiry dates; and
- 4° Respective conditions of storage.

CHAPTER IV : FINAL PROVISIONS

Article 14

All previous provisions contrary to this order are repealed.

Article 15 :

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

Done at Kigali, 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)