

**MINISTERIAL DECREE N° 20/11 OF 03/05/2005 OF GOVERNING THE COMPOSITION,  
ORGANISATION AND OPERATION OF THE NATIONAL COMMITTEE FOR  
PHARMACEUTICAL ESTABLISHMENT IMPLEMENTATION**

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 governing the pharmaceutical art, especially in its articles 11 and 13 ;

After consideration and adoption by the Cabinet in its session of 26<sup>th</sup> January 2005;

**ORDERS :**

**Article One :**

The National Committee for pharmaceutical establishment implementation, here in after the “Committee” is an organ of the Ministry having health in its attributions and under the authority of the Minister.

**Article 2 :**

The Committee is particularly responsible for the following :

- 1° Classify retail pharmacies from pharmaceutical stores and pharmaceutical institutions based on the criteria defined in the present ministerial order,
- 2° Examine application files lodged for either the establishment or transfer or seizure of pharmaceutical institutions and advise the Minister with health in his attributions accordingly.

**Article 3 :**

The Committee is composed of eight members:

- 1° The Director of pharmacy in the Ministry having health in its attributions, the Chairperson;
- 2° The Representative of the Ministry having commerce in its attributions , the Vice Chairperson;
- 3° The Pharmacist Inspector in the Ministry having health in its attributions, the Secretary;
- 4° The consumers representative,
  - 5° The in-charge of quality health-care in the Ministry having health in its attributions, member.
- 6° Two representatives of pharmacists in-charge of pharmacies open to public, nominated by the Minister having health in his attributions;
- 7° One representative of pharmacists in-charge of pharmacies closed to public, nominated by the Minister having health in his attributions;
- 8° Two representatives of pharmacists in-charge of whole-sale pharmaceutical institutions, nominated by the Minister having health in his attributions;

The tenure of office of the nominated members is three (3) years renewable.

**Article 4 :**

The Committee meets once in three months or variably at many times upon the chairman’s request or the vice-chairman’s demand in case the chairman is absent or unable to attend. The invitation for the meeting is to be sent to the respective members at least within eight working days before the date of the planned meeting.

The Committee can not duly convene (meet and take up decision) when the quorum is less than 2/3 of its entire members.

If the quorum is not made, the meeting can be postponed until fifteen days. Invitations should be sent to members at least within **eight working days** before the date planned for the next meeting. This time, the Committee shall hold the meeting irrespective of the number of members present.

Decisions made are based on the majority vote, but in case of parity the chairman's vote shall count two votes.

If the Committee deems it necessary to invite a resourceful person as a consultant then it can be done while the meeting is in progress.

**Article 5 :**

The response to the application file must be ready back at least within four (4) months after having been lodged in the Ministry with health in its attributions.

The Committee's views on the approved application files is forwarded to the Minister having health in his attributions at least within 10 working days after the meeting.

The Minister finally grants the approval and informs the applicants of the decision made in writing. However, any decision made contrary to the Committee's views must be subjected to prior justification.

**Article 6 :**

The applicant can request the Committee to re-examine his application file. The application shall again be addressed to the Minister with health in his attributions at least within eight (8) working days that follows the minister's written response to his first application file.

The Committee shall re-examine the application with priority and shall, upon completion, return their written views to the Minister with health in his attributions at least within five (5) days after the reception. The decision taken by the Minister, therefore, shall be final.

**Article 7 :**

As for retail pharmacies open to public or private pharmaceutical stores, their establishment should be in line with the following guiding principles:

- 1° Their distribution should allow the population's easy geographical access to drugs;
- 2° Ensure the best pharmaceutical services to the population.

**Article 8 :**

In case, a new retail pharmacy has to be established near a pharmaceutical store, that is, up on the recommendations of the respective committee, the directorate of pharmacies has therefore to inform the owner that his approval shall have to remain valid for a period of 2 years.

**Article 9 :**

The Committee's operational costs shall be provided by the Ministry with health in its attributions, using its ordinary budget as required by the existing rules and regulations.

**Article 10 :**

All previous provisions contrary to this decree are repealed.

**Article 11 :**

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

Done at Kigali, 03<sup>rd</sup> 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)