

MINISTERIAL DECREE N° 20/13 OF 03/05/2005 RELATED TO THE INSPECTION OF PHARMACIES

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, particularly in its article 84 (5);

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

DECREED :

Article one :

The present decree determines the mission of the inspector of pharmacies and conditions under which the missions can be carried-out.

Article 2 :

Inspectors of pharmacies are qualified staff/personnel, able to inspect the manner in which the existing rules and regulations pertaining to pharmaceutical products are abided by.

They can visit any place or area where pharmaceutical activities are legally or illegally practised.

Article 3 :

All holders of drug-stocks or stocks of other related pharmaceutical products are required to present to the inspector of pharmacies such products, together with other documents required by the existing law in force.

If the inspector of pharmacy deems it necessary, he can hold these documents against charges alleged to them.

Article 4 :

As in the case of a pharmaceutical institution, the inspectors of pharmacies, having been presented the quality control certificates of pharmaceutical products, justifying the level of their quality:

1° In case of a vivid evidence indicating the removal of the products or any alterations, of the proof needed, inspectors reserve the right to enter anywhere and any time except in private homes.

2° During inspectors' visits, the pharmacy in question can be opened by the owner himself, or his official representative or the pharmacist in-charge of either the enclosure, the premises, documents or locked buildings but needed for inspection.

If the proprietor refuses to comply with the inspector's demands, the inspector concerned shall therefore affix a seal on the pharmacy's door.

Without prejudice to the above paragraph, the inspector of pharmacies shall have the right to investigate, upon presentation of a search warrant obtainable from the Provincial Prosecutor or the Prosecutor of Kigali City enabling him to search even in individual private homes. In this case, however, he has to be accompanied by a member of the police force.

Article 5 :

The inspector shall be held responsible for any damage, loss or spoils of any kind, caused during the course of investigating the contravention of the law related to the pharmaceutical art.

Article 6 :

Within the framework of the mission, once the inspector observes any breach of law related to pharmaceutical art, and possible measures to be taken, he then states them in the records of his inspection.

Records of the inspectors, concerning the nature, circumstances that led to such a breach of law, the time and the place in which the law was contravened as well as the apparent tangible evidence likely to put at stake the presumed culprits.

Inspectors' records end with a written oath and stating as follows : "I here-by swear that the present minutes are correct."

The records are then sent to the Provincial Prosecutor or the Prosecutor of Kigali City in a closed plea and a copy of the original sent to the Minister with health in his attributions at least within 7 days from the date when the inspectors detected such a breach of law.

Equally, a copy of the same is sent to the presumed culprit.

Article 7 :

In case sampling is carried out on the pharmacy by the inspector of pharmacies concerned, such sampling must include three main samples and these samples must, in all possible ways, be made identical.

Samples should, therefore, be put in an envelop and sealed by the pharmacy's representative in a manner, that nothing is virtually altered, deducted or added thereon. On the outer-surface of the envelop, substances contained should be indicated and the type of drugs on which the sampling is done. The inspector of pharmacies concerned shall equally affix, again on the outer-surface of the envelop, a specific number of its kind, meant for the purpose.

The inspector of pharmacies who carries out the sampling, calls on the proprietor or the stock-holder of the pharmaceutical substances or of the drugs to be affixed for the samples and a particular date of the day. He/she signs under his/her own hand.

The first sample should be taken to a recognised laboratory. The second should be given to the proprietor, who is indeed, the one responsible for the seal, and the last shall be reserved for the department of pharmaceutical inspection for the second test.

The sample to be tested shall therefore be forwarded to the Ministry having Health in its attributions, which in return sends it to an approved pharmaceutical laboratory at least within a period of five working days. Lastly, the outcome of the laboratory test shall be sent to the proprietor.

Article 8 :

Once taxes are levied, the concerned inspector of pharmacies draws up minutes immediately, have them signed by first himself, the proprietor of the pharmacy in question and lastly, the offender. If the latter refuses to obey, his refusal is then included in the minutes.

These written minutes equally entail cost-estimates of the tax levied on the sample. The offender shall be compensated the amount owed to him, or the quantity of his pharmaceutical products seized, if proved to conform to the laboratory test carried-out.

In case of criminal procedures, all sampling charges levied on the samples and on the tests carried-out shall be considered as legal costs and met by the losing party.

Article 9 :

Once drugs or other pharmaceutical products are proved to have been deteriorated, deformed, altered or, in any way not conforming to the existing rules and regulations and the concerned recognises it, the inspectors of pharmacies can, by consent of people involved, remove from the defaulters, the altered drugs and destroy them.

If the defaulters do not agree to the proposed destruction, or to the removal of such deformed products, the inspectors of pharmacies concerned can have the products sealed. In this case, the inspector can take sample of the products to the approved laboratory. Based on the out-come of the test carried-out, he can either seal the products tested, or seize them.

Article 10 :

In breach of the law, minutes accrued from the inspection carried-out are thence sent to the Provincial Prosecutor or the Prosecutor of Kigali City. A copy shall be sent to the alleged offender, at least within a period of seven working days.

But if such contravention of the existing law causes concern to the public health, the Provincial Prosecutor or the Prosecutor of Kigali City can either make an order for the confiscation of drugs or the products deteriorated, deformed, altered or non-conforming to the acceptable norms.

The products confiscated and tested, prove to meet the norms required, or when the beholder of the products in question remain answerable to the breach of law committed earlier, the Provincial Prosecutors or the Prosecutor of Kigali City shall seize the products.

The place where such legally withheld products are kept, is determined by the Provincial Court or the Court the City of Kigali.

Article 11 :

All previous provisions contrary to this Decree are repealed.

Article 12 :

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

Done at Kigali, the 03rd 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)