L.N. 398 of 2005

MEDICINES ACT, 2003
(ACT NO. III OF 2003)

Authorization of Dispensing of Medicinal Oxygen from Premises other than a Pharmacy Rules, 2005

IN exercise of the powers conferred by article 79(2) of the Medicines Act, 2003, hereinafter referred to as "the Act", the Licensing Authority has made the following rules:–

Title.

1. The title of these rules is the Authorization of Dispensing of Medicinal Oxygen from Premises other than a Pharmacy Rules, 2005.

Dispensing of medical oxygen.

2. Medicinal oxygen shall not be dispensed from premises other than a pharmacy unless there is an authorization issued by the Licensing Authority and subject to such conditions set by the said Authority.

Granting of authorization.

3. (1) An authorization shall not be granted unless there is a written request by the applicant addressed to the Licensing Authority.

(2) All details of the intended operations must be submitted, including:

(a) the name and address of the applicant;

(b) the address of the premises that are to be used for such purpose;

(c) the equipment and control facilities;

(d) information, documentation or evidence to prove that the premises is suitable and adequate, and that there are suitable facilities, installations and equipment so as to ensure proper conservation and dispensing of the product;

(e) the name and address of a managing pharmacist who shall be professionally responsible for all activities;

(f) any other information, documentation, or evidence as may be requested by the Licensing Authority.

Conditions of authorization.

4. (1) The authorization shall only be applicable to the dispensing of the medicinal oxygen from such site as is indicated therein.

(2) Such authorization shall not be transferable.

Validity and renewal of authorization.

5. (1) An authorization shall be issued for a period of one year and shall terminate to be applicable upon its expiry.

(2) The authorization can be renewed following a written request to the Licensing Authority, to be submitted at least three months before expiry of the validity period.

Responsibility of managing pharmacist.

6. (1) A managing pharmacist shall be responsible for the dispensing of the medicinal oxygen and shall do so against the presentation of a prescription.

(2) The managing pharmacist shall follow any criteria and conditions for the dispensing of medicinal oxygen as may be laid down by the Licensing Authority from time to time.

Rights pertaining to Licensing Authority.

7. The Licensing Authority shall have the right to amend, suspend or revoke any authorization if:

(a) any matter stated in the application on which the authorization was issued is found to be false or incomplete;

(b) a material change of circumstances has occurred in relation to any of those matters;

(c) the provisions of the authorization have been contravened by the authorization holder;

(d) any other circumstance occurs as established by or under the Act.

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