



ZAMBIA MEDICINES REGULATORY AUTHORITY

Take note that the Zambia Medicines Regulatory Authority (ZAMRA) has amended the Guideline on Establishment of a Pharmaceutical Retail Business, 2020 following approval by the ZAMRA Board.

Guideline on Establishment of a Pharmaceutical Retail Business (Amendment), 2023

1. This Guideline may be cited as the Guideline on Establishment of a Pharmaceutical Retail Business (Amendment), 2023 and shall be read as one with the Guideline on Establishment of a Pharmaceutical Retail Business, 2020, in this Guideline referred to as the principal Guideline.
2. Guideline 3.3.1 of the principal Guideline is amended by the deletion of the words “physically be present to” immediately after word shall.
3. The principal Guideline is amended by the deletion of Guideline 3.3.2 and substitution therefor of the following:

3.3.2 A registered pharmacy shall engage the services of a full-time registered pharmacist as a responsible person, except that the responsible person shall not be –
 - (a) in full-time employment elsewhere;
 - (b) on leave, for less than six months, from a full-time job; or
 - (c) on full time educational studies.
4. The principal Guideline is amended by the insertion of following new Guideline immediately after Guideline 3.3.2
 - 3.3.2.1 Where a Locum Pharmacist is to stand in for the Responsible Person for a considerable period of time, the Locum Pharmacist shall be subject to the restrictions imposed on the responsible person.

5. Guideline 5.1 of the principal Guideline is amended by the deletion of the word “be physically present to” and insertion of the word “and control” immediately after the word “manage”.
6. The principal Guideline is amended by the deletion of Guideline 6.15 and substitution therefor of the following:

6.15 The following partition for the premises shall apply —

(a) In the case of for a pharmacy with a closed dispensary:

- (i) front shop: minimum size of 16 m²;
- (ii) dispensary: minimum size of 12 m²; with minimum width of 3m;
- (iii) total space: minimum size of 28 m²; and
- (iv) the dispensary can be used as consultation room

(b) In the case of a pharmacy with an open dispensary:

- (i) front shop: minimum size of 16m²;
- (ii) dispensary: minimum size of 9m²;
- (iii) office, consultation room: minimum size of 4m²;
- (iv) total minimum size of 29m²; and
- (v) store room: to be optional.

(c) For purposes of Guideline 6.15 (a) and (b) all pharmaceutical retail premises duly authorized to operate shall conform to the minimum requirements on relative partitions within a period of 2 years from the date of publication of this amendment.