

STATUTORY INSTRUMENTS SUPPLEMENT
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S T A T U T O R Y I N S T R U M E N T S

2021 No. 39.

**The National Drug Policy and Authority (Certificate of
Suitability of Premises) (Amendment) Regulations, 2021**
*(Under Section 64 of the National Drug Policy and Authority Act,
Cap. 206)*

IN EXERCISE of the powers conferred upon the Minister responsible for health by section 64 of the National Drug Policy and Authority Act and on the advice of the National Drug Authority, these Regulations are made this 16th day of June, 2021.

1. Title

These Regulations may be cited as The National Drug Policy and Authority (Certificate of Suitability of Premises) (Amendment) Regulations, 2021

2. Amendment of S.I 36 of 2014

The National Drug Policy and Authority (Suitability of Premises) Regulations, 2014 are amended—

- (a) in regulation 3 by numbering the provision as (1) and inserting immediately after subregulation (1) the following—

“(2) The distance of the proposed location from an existing licensed seller, retail pharmacy or wholesale pharmacy, as the case may be, shall be the distance

prescribed in the National Drug Policy and Authority (Licensing) (Amendment) Regulations, 2021.”;

- (b) in regulation 4 by inserting immediately after subregulation (2), the following—

“(3) A certificate of suitability of premises issued under this regulation shall—

- (a) for premises for the manufacture of drugs, be in the format in Forms 9A in the Schedule to these Regulations;
- (b) for premises for a wholesale pharmacy, be in the format in Form 10A in the Schedule to these Regulations;
- (c) for premises for a retail pharmacy, be in the format in Form 11A in the Schedule to these Regulations; and
- (d) for premises for a licensed seller, be in the format in Form 12A in the Schedule to these Regulations.”;

- (c) in regulation 5 by inserting immediately after subregulation (4), the following—

“(5) The Authority shall only consider an application for a certificate of suitability of premises where the location of the premises for which the application is made, is approved by the Authority under regulation 3 of the principal Regulations.”; and

- (d) in the Schedule—

- (i) by inserting immediately after Form 9 the following—

“FORM 9A

Regulation 4 (3)

DRUG

NATIONAL



AUTHORITY

General Certificate of Suitability of Premises for Manufacturing Drugs
*(Issued under Section 17 of the Act and Regulation 4(2) of the National
Drug Policy and Authority Certificate of Suitability of Premises)
Regulations 2014)*

This is to certify that the premises of:

.....
at the *(physical location)*
Postal Address:.....
.....
TIN:

**are considered suitable for carrying on the business of
Manufacturing of Drugs**

Premise No.

Issue Date Valid up to.....



.....

FOR THE AUTHORITY

**This Certificate must be prominently
displayed in the premises to which it
refers.”**

(ii) by inserting immediately after Form 10, the following—

“FORM 10A

Regulation 4 (3)

DRUG

NATIONAL



AUTHORITY

**General Certificate of Suitability of
Premises for Wholesale Pharmacy**

*Issued under Section 17 of the Act and Regulation 4(2) of the National
Drug Policy and Authority (Certificate of Suitability of Premises)
Regulations 2014*

This is to certify that the premises of:

.....

at :..... *(physical location)*

Postal Address:.....

TIN:

**are considered suitable for carrying on the business of
Wholesale Pharmacy**

Premise No.

Issued Date Valid up to.....



.....
FOR THE AUTHORITY

**This Certificate must be prominently
displayed in the premises to which it
refers.”**

(iii) by inserting immediately after Form 11, the following—

“FORM 11A

Regulation 4 (3)

DRUG

NATIONAL



AUTHORITY

**General Certificate of Suitability of
Premises for Retail Pharmacy**

*Issued under Section 17 of the Act and Regulation 4(2) of the National
Drug Policy and Authority (Certificate of Suitability of Premises)
Regulations 2014*

This is to certify that the premises of:

.....

at : (physical location)

Postal Address:.....

.....

TIN :

**are considered suitable for carrying on the business of
Retail Pharmacy**

Issued Date Valid up to.....



.....

FOR THE AUTHORITY

**This Certificate must be prominently
displayed in the premises to which it
refers.”**

(iv) by inserting immediately after Form 12, the following—

“FORM 12A

Regulation 4 (3)

DRUG



NATIONAL

AUTHORITY

**Limited Certificate of Suitability
of Premises for operating as a licensed seller**

*(Issued under Section 17 of the Act and Regulation 4(2) of the National
Drug Policy and Authority Certificate of Suitability of Premises)
Regulations 2014)*

This is to certify that the premises of:

.....

at :..... *(physical location)*

Postal Address:.....

TIN:

**are considered suitable for carrying on the business of
Operating as a licensed seller**

Premise No.

Issued Date Valid up to.....



.....

FOR THE AUTHORITY
**This Certificate must be prominently
displayed in the premises to which it
refers.”**

HON. DR. ACENG JANE RUTH OCERO,
Minister for Health