BELIZE:

FOOD AND DRUGS (REGISTRATION, LICENSING AND INSPECTION)(AMENDMENT) REGULATIONS, 2025

ARRANGEMENT OF PARAGRAPHS

BELIZE:

STATUTORY INSTRUMENT

No. 136 of 2025

REGULATIONS made by the Minister responsible for Health in exercise of the powers conferred upon him by section 55 of the Food and Drugs Act, Chapter 291 of the Substantive Laws of Belize, Revised Edition 2020, and all other powers thereunto him enabling.

(Gazetted 4th October, 2025)

1. These Regulations may be cited as the **Citation.**

FOOD AND DRUGS (REGISTRATION, LICENSING AND INSPECTION)(AMENDMENT) REGULATIONS, 2025,

and shall be read and construed as one with the Food and Drugs (Registration, Licensing and Inspection) Regulations, which as amended, is hereinafter referred to as the principal Act. **Sub. Leg, 2020 Edn. CAP. 291 p. 130 S.I. 41 of 2021.**

2. The principal Regulations are amended in regulation 4– **Amendment of regulation 4.**

(a) in sub-regulation (1)(h), by deleting the words "one hundred" and substituting the words "two hundred"; and

(b) in sub-regulation (1A)(b), by deleting the words "five hundred" and substituting the words "one hundred".

3. The principal Regulations are amended in Schedule 3– **Amendment of Schedule 3.**

(a) by deleting from the list of National Regulatory Authorities the following–

NRA Name	Region/Country
"Central Drugs Standard Control Organisation (CDSCO)	India"

; and

(b) by inserting the following National Regulatory Authorities in the proper alphabetical order by the Region/Country–

"NRA Name	Region/Country
National Administration of Drugs, Foods and Medical Devices (ANMAT)	Argentina
Public Health Institute of Chile (ISP)	Chile
Center for State Control of Medicines, Medical Equipment and Devices (CECMED)	Cuba
Spanish Agency of Medicines and Medical Devices (AEMPS)	Spain
Technical Evaluation Group (GEOT)	Council of Ministers of Health of Central America and The Dominican Republic (COMISCA)
Central American Health Regulation Agency	Council of Ministers of Health of Central America and The Dominican Republic (COMISCA)
World Health Organisation (WHO) Pre-Qualified Medicines	WHO"

Transitional.

4.–(1) The application for registration fees which are required by regulation 4(1)(h) and 4(1A)(b) shall not be required for the period of six months from the date of commencement of these Regulations.

(2) During the period specified in sub-regulation (1), every person who has commercialized a drug that is not registered shall, if that drug is currently available on the market and is being re-imported without registration, register that drug under these Regulations notwithstanding the importation prior to commencement of these Regulations.

(3) Compliance under sub-regulation (2) shall be considered without the institution of proceedings in accordance with regulation 3(3).

Commencement.

5. These Regulations shall come into force on the 15th day of November, 2025.

MADE by the Minister responsible for Health this 30th day of September, 2025.

(HON. KEVIN BERNARD)
Minister of Health and Wellness
(Minister responsible for Health)

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