



The President
Palikir, Pohnpei
Federated States of Micronesia



June 21, 2022

The Honorable Wesley W. Simina
Speaker
Twenty-Second Congress
Federated States of Micronesia
Palikir, Pohnpei FM 96941

PRESIDENTIAL COMM. NO. 22-287
FSM CONGRESS

Dear Speaker Simina:

I am pleased to transmit the following act, which I have signed to become Public Law No. 22-135 :

Congressional Act No. 22-111, entitled: "AN ACT TO FURTHER AMEND TITLE 54 OF THE CODE OF THE FEDERATED STATES OF MICRONESIA (ANNOTATED), AS AMENDED, BY CREATING A NEW CHAPTER 10 TO ESTABLISH THE FSM PHARMACEUTICAL IMPORT CONTROL ACT OF 2022, ESTABLISH IMPORT CONTROLS ON THE IMPORTATION OF PHARMACEUTICALS INTO THE FSM, REQUIRE ALL ENTITIES IMPORTING PHARMACEUTICALS INTO THE FSM TO HAVE A VALID PHARMACEUTICAL UNIT LICENSE AND PHARMACEUTICAL PRODUCT REGISTRATION APPROVAL IN ORDER TO IMPORT PHARMACEUTICALS, AUTHORIZE THE SECRETARY OF FINANCE TO FINE ANY ENTITY IMPORTING PHARMACEUTICALS IN VIOLATION OF THIS ACT, AND FOR OTHER PURPOSES."

I thank the 22nd FSM Congress for the passage of this act.

Sincerely,

David W. Panuelo
President

xc: Chief Justice, FSM Supreme Court



Office of the Chief Clerk

CONGRESS OF THE FEDERATED STATES OF MICRONESIA

P.O. Box PS 3

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PRESIDENTIAL COMM. NO. 22-287
FSM CONGRESS

May 30, 2022

His Excellency David W. Panuelo
President
Federated States of Micronesia
Palikir, Pohnpei FM 96941

RECEIVED
MAY 30 2022
Office of the
President FSM

Dear President Panuelo:

I have the honor to transmit herewith Congressional Act No. 22-111, "AN ACT TO FURTHER AMEND TITLE 54 OF THE CODE OF THE FEDERATED STATES OF MICRONESIA (ANNOTATED), AS AMENDED, BY CREATING A NEW CHAPTER 10 TO ESTABLISH THE FSM PHARMACEUTICAL IMPORT CONTROL ACT OF 2022, ESTABLISH IMPORT CONTROLS ON THE IMPORTATION OF PHARMACEUTICALS INTO THE FSM, REQUIRE ALL ENTITIES IMPORTING PHARMACEUTICALS INTO THE FSM TO HAVE A VALID PHARMACEUTICAL UNIT LICENSE AND PHARMACEUTICAL PRODUCT REGISTRATION APPROVAL IN ORDER TO IMPORT PHARMACEUTICALS, AUTHORIZE THE SECRETARY OF FINANCE TO FINE ANY ENTITY IMPORTING PHARMACEUTICALS IN VIOLATION OF THE ACT, AND FOR OTHER PURPOSES", which was passed by the Twenty-Second Congress of the Federated States of Micronesia, Fourth Regular Session, 2022, by a two-thirds vote of all the State delegations as required and as duly certified.

Sincerely yours,

A handwritten signature in black ink, appearing to be "Jessicalynn Reyes", written over a horizontal line.

Jessicalynn Reyes
Chief Clerk, Congress of the
Federated States of Micronesia

Enclosures



PRESIDENTIAL COMM. NO. 22-287
FSM CONGRESS

TWENTY-SECOND CONGRESS OF THE
FEDERATED STATES OF MICRONESIA
FOURTH REGULAR SESSION
MAY 04 – [23] 27, 2022
(EXTENDED BY C.R. NO. 22-130, ADOPTED 05/23/22)

An Act

TO FURTHER AMEND TITLE 54 OF THE CODE OF THE FEDERATED STATES OF MICRONESIA (ANNOTATED), AS AMENDED, BY CREATING A NEW CHAPTER 10 TO ESTABLISH THE FSM PHARMACEUTICAL IMPORT CONTROL ACT OF 2022, ESTABLISH IMPORT CONTROLS ON THE IMPORTATION OF PHARMACEUTICALS INTO THE FSM, REQUIRE ALL ENTITIES IMPORTING PHARMACEUTICALS INTO THE FSM TO HAVE A VALID PHARMACEUTICAL UNIT LICENSE AND PHARMACEUTICAL PRODUCT REGISTRATION APPROVAL IN ORDER TO IMPORT PHARMACEUTICALS, AUTHORIZE THE SECRETARY OF FINANCE TO FINE ANY ENTITY IMPORTING PHARMACEUTICALS IN VIOLATION OF THE ACT, AND FOR OTHER PURPOSES.

INTRODUCED BY SENATOR: FERNY S. PERMAN

DATE: MAY 04, 2022

REFERRED TO: COMMITTEE ON HEALTH AND SOCIAL AFFAIRS

S.C.R. NO. 22-34 – MAY 20, 2022

FIRST READING: – MAY 23, 2022

SECOND READING: – MAY 24, 2022

A handwritten signature in black ink, appearing to read "Jessicalynn Reyes", is written over a horizontal line.

Jessicalynn Reyes
Chief Clerk, FSM Congress



Office of the Speaker

CONGRESS OF THE FEDERATED STATES OF MICRONESIA

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PRESIDENTIAL COMM. NO. 22-287
FSM CONGRESS

ACT NO. 22-111

(CONGRESSIONAL BILL NO. 22-165, C.D.1)

We hereby certify that on May 24 the foregoing act passed
Second and Final Reading of the Twenty-Second Congress of the
Federated States of Micronesia, Fourth Regular Session, 2022,
by a two-thirds vote of all the State delegations as required
under article IX, section 20, of the Constitution of the
Federated States of Micronesia.

A handwritten signature in black ink, appearing to be "W. Simina", with a checkmark to its left.

Wesley W. Simina
Speaker
Congress of the
Federated States of Micronesia

A large, stylized handwritten signature in black ink, appearing to be "J. Reyes", with a long horizontal line extending to the right.

Jessicalynn Reyes
Chief Clerk
Congress of the
Federated States of Micronesia

AN ACT

To further amend title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, by creating a new chapter 10 to establish the FSM Pharmaceutical Import Control Act of 2022, establish import controls on the importation of pharmaceuticals into the FSM, require all entities importing pharmaceuticals into the FSM to have a valid Pharmaceutical Unit license and pharmaceutical product registration approval in order to import pharmaceuticals, authorize the Secretary of Finance to fine any entity importing pharmaceuticals in violation of the Act, and for other purposes.

BE IT ENACTED BY THE CONGRESS OF THE FEDERATED STATES OF MICRONESIA:

1 Section 1. Title 54 of the Code of the Federated States of
2 Micronesian (Annotated), as amended, is hereby further amended by
3 creating a new chapter 10 entitled: "FSM Pharmaceutical Import
4 Control Act of 2022".

5 Section 2. Chapter 10 of title 54 of the Code of the
6 Federated States of Micronesia (Annotated), as amended, is hereby
7 amended by inserting a new subchapter 1 entitled: "General
8 Provisions".

9 Section 3. Chapter 10 of title 54 of the Code of the
10 Federated States of Micronesia (Annotated), as amended, is hereby
11 amended by inserting a new section 1001 of subchapter 1 to read as
12 follows:

13 "Section 1001. Short title. This Act may be referred
14 to as the Pharmaceutical Import Control Act.".

15 Section 4. Chapter 10 of title 54 of the Code of the
16 Federated States of Micronesia (Annotated), as amended, is hereby

1 amended by inserting a new section 1002 of subchapter 1 to read as
2 follows:

3 "Section 1002. Statement of Policy. It is hereby
4 declared as a policy of the Federated States of
5 Micronesia: The enforcement of import controls on all
6 pharmaceuticals is necessary to ensure acceptable
7 standards of quality, safety and efficacy of
8 pharmaceuticals entering the country; and ensure the
9 practices of all persons, businesses, entities and
10 establishments involved in the importation of
11 pharmaceuticals into the FSM comply with the acceptable
12 standards of quality, safety and efficacy."

13 Section 5. Chapter 10 of title 54 of the Code of the
14 Federated States of Micronesia (Annotated), as amended, is hereby
15 amended by inserting a new section 1003 of subchapter 1 to read as
16 follows:

17 "Section 1003. Definitions: For the purposes of this
18 title, the following terms shall be given the meanings
19 described herein:

20 (1) "Active Pharmaceutical Ingredient" (API) is the
21 chemical substance contained in a pharmaceutical, which
22 is responsible for its therapeutic effect. Some
23 pharmaceuticals contain more than one active ingredient
24 (combination product).

25 (2) "Assistant Secretary of Customs" means the

Assistant Secretary for the FSM Customs and Tax Administration under the FSM Department of Finance and Administration.

(3) "Authorized port of entry" means a port of entry designated by the Secretary of Justice under Section 202 of Title 18 of the Code of the FSM.

(4) "Certificate of pharmaceutical product (CPP)" means a certificate issued by the authorized body of the exporting country that satisfies the pharmaceutical verification format standards to permit importation into the FSM as determined by the Secretary of Health.

(5) "Competent jurisdictions" means countries with stringent and operational regulatory system where medicines can be imported into the FSM as determined by the Secretary of Health.

(6) "Customs Administration" means the Customs and Tax Administration under the FSM Department of Finance and Administration.

(7) "Department of Health" means the Department of Health and Social Affairs.

(8) "Distribution" means the division and movement of pharmaceuticals from the port of entry to the Establishment or end user thereof, by means of various transport methods or storage.

(9) "Distributor" means an individual, company or

1 legal entity distributing or seeking to distribute a
2 pharmaceutical.

3 (10) "Donation" means the act by which organizations,
4 institutions, international development partners, non-
5 government organizations and other legal entities
6 provide pharmaceuticals to the FSM for free and for
7 specific use, such as in the case of emergency or for
8 humanitarian purposes.

9 (11) "Establishment" means an entity in the FSM that
10 engages in the importation of pharmaceuticals and/or
11 active pharmaceutical ingredients into the FSM, including
12 but not limited to:

- 13 a. Wholesalers;
- 14 b. Distributors;
- 15 c. Pharmacies;
- 16 d. Importers;
- 17 e. Exporters;
- 18 f. Manufacturers; and
- 19 g. Warehouse operators.

20 (12) "Exportation" means the lawful process of sending
21 medicines out of the FSM by, sea or air.

22 (13) "Exporter" means an individual, company or legal
23 entity that exports pharmaceuticals.

24 (14) "FSM Approved Medicines List" means a list of
25 pharmaceuticals determined by the Secretary of Health to

1 meet the needs of the FSM population and satisfy the
2 pharmaceutical product registration approval criteria for
3 importation into the FSM.

4 (15) "Importation" means the lawful process of
5 bringing medicines into the FSM, by sea or air.

6 (16) "Importer" means an individual, company or
7 similar legal entity importing or seeking to import
8 pharmaceuticals.

9 (17) "Inspect" or "Inspection" means an official
10 examination, usually conducted on-site by the relevant
11 authority to determine compliance to regulations,
12 standards and practices by Establishments and/or any
13 other entity engaged in the import of pharmaceuticals
14 into the FSM at the ports of entry.

15 (18) "Manufacturer" means an individual, company or
16 legal entity that engages in the operation of procuring
17 supply, production, packaging, repackaging, labeling,
18 relabeling, quality control, release, storage and
19 distribution of active pharmaceutical ingredients and
20 related controls.

21 (19) "Over-the-counter medicines (non-prescription
22 medicines)" means medicines sold from licensed dealers
23 without professional supervision and prescription that
24 are suitable for self-medication for minor disease and
25 symptoms.

(20) "Pharmaceutical" means any substance or medical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. The term "pharmaceutical" includes any pharmaceutical product, drug, medicine, vaccine, biopharmaceuticals, blood and blood products, active pharmaceutical ingredients, and any other products with therapeutic effect.

(21) "Pharmaceutical Unit" means the Pharmaceutical Unit under the FSM Department of Health and Social Affairs.

(22) "Prescription" means an order mostly in written form by a licensed health care professional to a pharmacist or other therapist for a pharmaceutical or medicine to be provided to the health care professional's patient.

(23) "Procurement" means the process of acquiring pharmaceuticals, including those obtained by purchase or donation.

(24) "Secretary of Health" means the Secretary of Health and Social Affairs.

(25) "Wholesale" means all activities consisting of procuring, holding, or supplying pharmaceuticals for import or export.

(26) "Wholesaler" means an individual, company or

1 similar legal entity engaged in the wholesale of
2 pharmaceuticals."

3 Section 6. Chapter 10 of title 54 of the Code of the
4 Federated States of Micronesia (Annotated), as amended, is hereby
5 amended by creating a new subchapter 2 entitled: "Scope of the
6 Law".

7 Section 7. Chapter 10 of title 54 of the Code of the
8 Federated States of Micronesia (Annotated), as amended, is hereby
9 amended by inserting a new section 1004 of subchapter 2 to read as
10 follows:

11 "Section 1004. Scope of Law.

12 (1) Pharmaceutical Products.

13 All pharmaceuticals imported into the FSM shall be
14 regulated under this Act. Any drug, medicine, or health
15 supplement imported into the FSM with a therapeutic claim
16 that is not scientifically verifiable shall be treated
17 and regulated as a pharmaceutical under this Act.

18 (2) Pharmaceutical Activities.

19 All Establishment pharmaceutical activities related to
20 the importation of pharmaceuticals into the FSM shall be
21 regulated at the ports of entry under this Act.

22 (3) Exempt Pharmaceuticals.

23 The regulation of pharmaceuticals and pharmaceutical
24 activities under this Act does not apply to natural or
25 indigenous medicines native to the FSM and

pharmaceuticals for personal use in accordance with
Section 1304(3) of Title 41 of the Code of FSM.

(4) Establishment Requirements for Importation.

Customs Administration shall only permit the import of
pharmaceuticals into the FSM by Establishments licensed
by the Pharmaceutical Unit with pharmaceutical product
registration and approval from the Pharmaceutical Unit at
authorized ports of entry. The Establishment shall
demonstrate to the Customs Administration its compliance
with Establishment licensure and all conditions on the
pharmaceutical product registration implemented by the
Pharmaceutical Unit pursuant to Chapter 13 of Title 41 of
the Code of the FSM."

Section 8. Chapter 10 of title 54 of the Code of the
Federated States of Micronesia (Annotated), as amended, is hereby
amended by creating a new subchapter 3 entitled: "Enforcement".

Section 9. Chapter 10 of title 54 of the Code of the
Federated States of Micronesia (Annotated), as amended, is hereby
amended by inserting a new section 1005 of subchapter 3 to read as
follows:

"Section 1005. Customs Administration Enforcement
Authority.

(1) The Customs Administration shall have the authority
to enforce Department of Health regulations on
Establishments importing pharmaceuticals under Chapter 13

of Title 41 of the Code of the FSM at all ports of entry.

(2) The Customs Administration shall inspect all pharmaceuticals at all ports of entry in order to implement and enforce this Act.

(3) The Assistant Secretary of Customs shall have the authority to deny entry and seize any pharmaceuticals at a port of entry:

(A) not in compliance with the import controls under Section 1006; and/or

(B) not at an authorized port of entry.

(4) The Customs Administration shall not seize and/or deny entry of exempt pharmaceuticals under Section 1004(3)."

Section 10. Chapter 10 of title 54 of the Code of the Federated States of Micronesia (Annotated), as amended, is hereby amended by inserting a new section 1006 of subchapter 3 to read as follows:

"Section 1006. Pharmaceutical Import Controls.

(1) The Assistant Secretary of Customs shall only permit the importation of pharmaceuticals by an Establishment with a valid license issued by the Pharmaceutical Unit under the following conditions:

(a) Pharmaceutical is on the FSM Approved Medicines List and from a competent jurisdiction as designated by the Secretary of Health; or

(b) Establishment has a valid pharmaceutical

1 product registration approval from the Pharmaceutical
2 Unit for the specific pharmaceutical.

3 (2) The Assistant Secretary of Customs shall require
4 all Establishments importing pharmaceuticals to present
5 the required documentation as determined by the Secretary
6 of Health, including but not limited to Establishment
7 licensure and pharmaceutical product registration, and
8 certificate of pharmaceutical product ("CPP"), to the
9 Customs Administration upon inspection at any port of
10 entry.

11 (3) The Customs Administration, in coordination with
12 the Pharmaceutical Unit, shall deny the importation of
13 expired pharmaceuticals, and/or pharmaceuticals with
14 falsified CPP.

15 (4) The Customs Administration shall prohibit the
16 import of any pharmaceutical and/or active pharmaceutical
17 ingredients by any manufacturer."

18 Section 11. Chapter 10 of title 54 of the Code of the
19 Federated States of Micronesia (Annotated), as amended, is hereby
20 amended by inserting a new section 1007 of subchapter 3 to read
21 as follows:

22 "Section 1007. Entry of Pharmaceuticals for Public
23 Health and Life-Saving Emergencies.

24 The Customs Administration shall only permit the
25 importation of a pharmaceutical not on the FSM Approved

1 Medicines List or not registered as a pharmaceutical
2 product with the Pharmaceutical Unit, if the
3 pharmaceutical is from a competent jurisdiction and upon
4 the Secretary of Health signed certification to Congress
5 that life-saving assistance, or welfare requires the
6 immediate entry of the pharmaceutical."

7 Section 12. Chapter 10 of title 54 of the Code of the
8 Federated States of Micronesia (Annotated), as amended, is hereby
9 amended by creating a new subchapter 4 entitled: "Administrative
10 Penalties".

11 Section 13. Chapter 10 of title 54 of the Code of the
12 Federated States of Micronesia (Annotated), as amended, is hereby
13 amended by inserting a new section 1008 of subchapter 4 to read as
14 follows:

15 "Section 1008. Administrative Penalties.

16 The Secretary of Finance has the authority to issue
17 administrative penalties of \$3,000 up to \$15,000 upon a
18 final finding that Establishment violated any provision
19 of this Act. The Establishment shall have the right to
20 request an administrative hearing in accordance with due
21 process procedures under Chapter 1 of Title 17 of the
22 Code of the FSM."

1 Section 14. This act shall become law upon approval by the
2 President of the Federated States of Micronesia or upon its
3 becoming law without such approval.

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7 June 21, 2022

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12 David W. Panuelo
13 President
14 Federated States of Micronesia
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