BILL NO. 38 OF 2021

A BILL

FOR AN ACT TO AMEND THE MEDICINAL PRODUCTS ACT 2011

ENACTED by the Parliament of the Republic of Fiji-

Short title and commencement

1.—(1) This Act may be cited as the Medicinal Products (Amendment) (No. 2) Act 2021.

(2) This Act comes into force on a date appointed by the Minister by notice in the Gazette.

Section 35 amended

2. Section 35(1) of the Medicinal Products Act 2011 is amended after "Board" by inserting ", except a medicinal product, poison or device or other specified product which in the opinion of the Minister, is safe for general use and which is specified by regulations made under this Act".

Office of the Attorney-General Suvavou House Suva

November 2021

MEDICINAL PRODUCTS (AMENDMENT) (NO. 2) BILL 2021 EXPLANATORY NOTE

(This note is not part of the Bill and is only intended to indicate its general effect)

1.0 BACKGROUND

- 1.1 The Medicinal Products Act 2011 (**'Act'**) provides for, *inter alia*, the regulation of the import, manufacture, export, supply, sale, advertising and promotion of medicinal products, devices, and poisons which are of acceptable quality, safety and efficacy.
- 1.2 Section 35 of the Act provides for the requirement to acquire a licence from the Fiji Medicinal Products Board (**'Board'**) in order to import, manufacture, export, store, distribute, sell or offer for sale any product regulated under the Act (**'product'**).
- 1.3 While the Minister responsible for health (**'Minister'**) is empowered to exempt certain products, which in the opinion of the Minister are safe for general use and specified by regulations made under the Act, the Minister may only make such an exemption in relation to their storage, distribution, sale or offer for sale. The Minister cannot make an exemption in relation to the import, manufacture or export of products.
- 1.4 The Medicinal Products (Amendment) (No. 2) Bill 2021 (**'Bill'**) therefore seeks to align the provisions in section 35 of the Act so that the Minister is also empowered to make exemptions in relation to the import, manufacture or export of products, in particular to make the importation of COVID-related equipment easily available at affordable prices.

2.0 CLAUSES

2.1 Clause 1 of the Bill provides for the short title and commencement. If passed by Parliament, the amending legislation will come into force on a date appointed by the Minister by notice in the Gazette.

2.2 Clause 2 of the Bill amends section 35(1) of the Act to empower the Minister to exempt certain products that are safe for general use to be imported, manufactured or exported without a licence from the Board.

3.0 MINISTERIAL RESPONSIBILITY

3.1 The Act comes under the responsibility of the Minister responsible for health and medical services.

A. SAYED-KHAIYUM Attorney-General