BILL NO. 44 OF 2022

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 (Budget Amendment) Act 2022.

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

(3) In this Act, the Medicinal Products Act 2011 is referred to as the "Principal Act".

Section 3 amended

2. Section 3 of the Principal Act is amended by—

(a) in the definition of "approved" after "Board", inserting ", Minister or Commission, as applicable"; and

(b) inserting the following new definition—

""Commission" means the Fijian Competition and Consumer Commission established under section 7 of the Fijian Competition and Consumer Commission Act 2010;".

Section 6 amended

3. Section 6(2) of the Principal Act is amended by—

(a) in paragraph *(e)*, deleting "or licences";

(b) in paragraph *(f)*, deleting "or licence"; and

(c) deleting paragraph *(g)*.

Section 7 amended

4. Section 7(1) of the Principal Act is amended by—

(a) in paragraph *(a)*, deleting "or licences"; and

(b) deleting paragraph *(b)*.

Section 22 amended

5. Section 22(1) of the Principal Act is amended by—

(a) in paragraph *(b)* deleting "licences and" and substituting "product";

(b) after paragraph *(b)*, inserting the following new paragraph—

"*(ba)* receive and process applications for licences and refer every application duly made to the Commission for decision;"; and

(c) in paragraph *(c)* after "Board", inserting "or Commission, as applicable,".

Section 23 amended

6. Section 23 of the Principal Act is amended by—

(a) in subsection (1), deleting "by the Board,"; and

(b) in subsection (2) after "Board", inserting "or Commission, as applicable".

Section 35 amended

7. Section 35 of the Principal Act is amended by deleting "Board" wherever it appears and substituting "Commission".

Section 40A inserted

8. The Principal Act is amended after section 40 by inserting the following new section—

"*General practitioners and dentists under PPP Scheme*

40A.—(1) Notwithstanding the provisions of this Part, a general practitioner or dentist may store and distribute medicinal products or devices, provided—

(a) the general practitioner or dentist is engaged under a PPP Scheme;

(b) the nearest pharmacy is not operating; and

(c) the medicinal products or devices distributed are sufficient only for a 24-hour period.

(2) The general practitioner or dentist must, when distributing medicinal products or devices, provide advice and counsel on the effective and safe use of the medicinal products or devices.

(3) Any general practitioner or dentist who distributes medicinal products or devices while the nearest pharmacy is operating commits an offence and is liable on conviction to a fine not exceeding $5,000.

(4) In this section—

"general practice" has the meaning given in section 119 of the Medical and Dental Practitioner Act 2010;

"general practitioner" means a medical practitioner who engages in general practice on his or her own account;

"medicinal products or devices" means the medicinal products or devices approved by the Permanent Secretary for storage and distribution under subsection (1); and

"PPP Scheme" means a public private partnership scheme with the Government, for the engagement of the following persons—

(a) general practitioners, as approved by the Government; and

(b) dentists practising on their own account, as approved by the Government.".

Section 51 amended

9. The Principal Act is amended by deleting section 51 and substituting the following—

"*Institution of prosecutions*

51. Except in relation to section 35, a prosecution for an offence under this Act or regulations may only be instituted with the sanction of the Board.".

Section 52 amended

10. Section 52(1) of the Principal Act is amended after "Board" by inserting "or Commission, as applicable".

Section 60 inserted

11. The Principal Act is amended after section 59 by inserting the following new section—

"*Transitional provision – Medicinal Products (Budget Amendment) Act 2022*

60. A person licensed under section 35 on or before the commencement of the Medicinal Products (Budget Amendment) Act 2022 must apply to the Commission for a new licence at least one month before the expiry of the existing licence.".

Office of the Attorney-General
Suvavou House
Suva

July 2022

MEDICINAL PRODUCTS (BUDGET AMENDMENT) BILL 2022

EXPLANATORY NOTE

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

1.0 BACKGROUND

1.1 The Medicinal Products Act 2011 (**'Act'**) provides for the protection of the health and safety of the public by regulating the import, manufacture, export, supply, sale, advertising and promotion of medicinal products, devices, poisons and similar products. The Act seeks to ensure that such products and devices are of acceptable quality, safety and efficacy.

1.2 The Act was enacted together with the Pharmacy Profession Act 2011 (**'Pharmacy Act'**) and these two Acts work in tandem to establish the regulatory framework for medicines and pharmacies. However, many private pharmacy services are only available at limited times or are not available, even in populated areas of Fiji. The anti-competitive nature of the legislative framework set out under the Act contributes to these limited services since it places *inter alia* the decision-making for pharmacy business matters in the hands of a select group of competing pharmacists.

1.3 The Medicinal Products (Budget Amendment) Bill 2022 (**'Bill'**) seeks to amend the Act to:

(a) address the anti-competitive nature of the Act to ensure that pharmacy businesses are able to compete more effectively; and

(b) provide for a wider reach of medical and dental services to the public through the engagement of general practitioners and dentists practising on their own account, under a public private partnership scheme with the Government of the Republic of Fiji (**'PPP Scheme'**).

1.4 The Bill seeks to address the indirect limits on competition in the Act by removing the Fiji Medicinal Products Board's (**'Board'**) role in licensing the import, manufacture, export, storage, distribution and sale of medicinal products, poisons and devices, and the licensing of business premises for these purposes. As the Board consists of registered pharmacists operating their own

pharmacy businesses, by allowing the Board to determine the stock as well as giving the Board access to the details of the operations of pharmacy businesses, the Act has created a system where some competing pharmacists have an unfair advantage over others. This is not a system which is conducive to fair and dynamic competition in this market and as such, the Act seeks to transfer the business and market control role of the Board to the Fijian Competition and Consumer Commission (**'FCCC'**). FCCC is a third-party independent regulator established under section 7 of the Fijian Competition and Consumer Commission Act 2010. FCCC possesses expertise in competition and market dynamics and is better placed to determine the business-related aspects of the pharmacy business market. The proposed amendment seeks to transfer business and market regulation from the Board to FCCC, to provide for accountability and transparency and to avoid any conflict of interest which may arise during the running of a pharmacy business in Fiji.

1.5 The Bill also seeks to broaden the availability of medical and dental services by, as a complement to the objectives of the PPP Scheme, empowering general practitioners and dentists engaged under the PPP Scheme to store and distribute medicinal products or devices approved by the Permanent Secretary for Health and Medical Services, provided the nearest pharmacy is not operating.

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 or dates appointed by the Minister by notice in the Gazette.

2.2 Clause 2 of the Bill amends section 3 of the Act to expand the definition of the term "approved" and insert the definition of the term "Commission", which is FCCC.

2.3 Clauses 3 to 6 of the Bill amend sections 6, 7, 22 and 23 of the Act to facilitate the amendments proposed in clause 7 of the Bill.

2.4 Clause 7 of the Bill amends section 35 of the Act to provide for the transition of the role, from the Board to FCCC, of licensing the import, manufacture, export, storage, distribution and sale of medicinal products, poisons and devices, and the licensing of business premises for these purposes.

2.5 Clause 8 of the Bill amends the Act by inserting a new section 40A to provide for the storage and distribution of medicinal products or devices by general practitioners and dentists engaged under the PPP Scheme.

2.6 Clause 8 of the Bill also amends the Act to provide that such general practitioners and dentists may only distribute medicinal products or devices if the nearest pharmacy is not operating, and the medicinal products or devices distributed are sufficient only for a 24-hour period.

2.7 Furthermore, clause 8 of the Bill amends the Act to ensure that when distributing medicinal products or devices, such general practitioners and dentists also provide advice and counsel on the effective and safe use of the medicinal products or devices.

2.8 Moreover, clause 8 of the Bill amends the Act to provide that such general practitioners and dentists who distribute medicinal products or devices while the nearest pharmacy is operating, commit an offence and are liable on conviction to a fine not exceeding $5,000.

2.9 Clause 9 of the Bill amends section 51 of the Act to exempt an offence under section 35 from the requirement to attain the Board's consent for prosecution. As FCCC will be carrying out the licensing role under section 35 of the Act, there is no need for the Board to consent to the initiating of proceedings for a breach of the licensing requirement.

2.10 Clause 10 of the Bill amends section 52 of the Act to enable the Minister for Health and Medical Services to consult the Commission as well for any licensing regulations made under the Act.

2.11 Clause 11 of the Bill amends the Act to insert a new section 60, which provides for the transition of the role, from the Board to FCCC, of licensing the import, manufacture, export, storage, distribution and sale of medicinal products, poisons and devices and the licensing of business premises for these purposes. The transitional provision requires all persons licensed under section 35 of the Act to reapply for a licence one month before the expiry of their existing licence.

3.0 MINISTERIAL RESPONSIBILITY

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

A. SAYED-KHAIYUM
Attorney-General

Price: $1.03 NITESH A. PRASAD, SERENDIB INVESTMENT PTE LTD, (Acting Government Printer), Suva, Fiji – 2022 44/A/22—269
Official Printer Since 2019