

INCOME TAX ACT 2015

Income Tax (Manufacture of Pharmaceutical Products Investment Package) Regulations 2019

IN exercise of the powers conferred on me by section 25A of the Income Tax Act 2015, I hereby make these Regulations—

PART 1—PRELIMINARY

Short title and commencement

1.—(1) These Regulations may be cited as the Income Tax (Manufacture of Pharmaceutical Products Investment Package) Regulations 2019.

(2) These Regulations come into force on 1 August 2019.

Laws to be read together

2. These Regulations shall *inter alia* be read together in conjunction with the—

- (a) Customs Act 1986 and the Customs Tariff Act 1986 in so far as it relates to customs and duties;
- (b) Excise Act 1986 in so far as it relates to excise; and
- (c) Value Added Tax Act 1991.

Interpretation

3. In these Regulations, unless the context otherwise requires—

“company” means a company registered under the Companies Act 2015;

“exempt goods” means raw materials, plant, machinery and equipment (including spare parts) required for the establishment of a business for the manufacture of pharmaceutical products;

“manufacture” includes the process of refining, manipulating and mixing a pharmaceutical product, including in its a raw state, but does not include the process that is carried out by a pharmacist in the lawful practice of his or her profession, and includes an existing manufacture of pharmaceutical products;

“manufacture of pharmaceutical products investment” means the development of a building or buildings for the manufacture of pharmaceutical products with capital investment (including the cost of support infrastructure and consultant fees but excluding the cost of land) over \$250, 000 and the project commences on or after 1 August 2019 and the building is completed within 24 months from the date the provisional approval is granted;

“manufacture of pharmaceutical products investment package” means the various exemptions, concessions and subsidies given under a manufacture of pharmaceutical products investment;

“manufacturer” means a person who manufactures pharmaceutical products and includes a person manufacturing pharmaceutical products as at 1 August 2019;

“Minister” means the Minister responsible for finance;

“pharmaceutical product” means a substance or product, not being an instrument, apparatus or appliance that is represented to achieve, or likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal and that is—

- (a) represented in any way to be, or that is, whether because of the way it is presented or for any other reason, likely to be taken to be for—
 - (i) therapeutic use;
 - (ii) use as an ingredient or component in the manufacture of medicines;

- (iii) use as a container or part of a container for medicines of a kind referred to in subparagraph (i) or (ii); or
- (b) included in a class of substances or products, the sole or principal use of which is or ordinarily is a—
 - (i) therapeutic use; or
 - (ii) use of a kind referred to in paragraph (a)(ii) or (iii) and includes substances and products under the Medicinal Products Act 2011, but does not include—
 - (A) substances or products declared under the Medicinal Products Act 2011 not to be medicinal products or not to be medicinal products when used, advertised or presented for supply in a specified way if the substances or products are used, advertised or presented for supply in that way;
 - (B) food;
 - (C) any herbal drug or medicine, or a homoeopathic medicine; or
 - (D) prohibited substances; and

“provisional approval” means a provisional approval granted under Part 2.

Objective

4. The purpose of these Regulations is to encourage investments in the manufacture of pharmaceutical products by the provision of financial inducements.

PART 2—MANUFACTURE OF PHARMACEUTICAL PRODUCTS INVESTMENT PACKAGE

Power to grant manufacture of pharmaceutical products investment package

5. The Minister or CEO may grant or refuse to grant a manufacture of pharmaceutical products investment package to a company which has completed a manufacture of pharmaceutical products investment and has complied with this Part.

Provisional approval

6.—(1) The Minister or CEO, as applicable, may after consulting the Minister responsible for health and medical services—

- (a) reject the application for provisional approval for a manufacture of pharmaceutical products investment package; or
- (b) grant provisional approval to such application, with or without any condition.

(2) The Minister or CEO, as applicable, must not grant provisional approval under subregulation (1) unless the Minister is satisfied that—

- (a) the application is for a manufacture of pharmaceutical products investment;
- (b) the company intends to complete and is capable of completing such manufacture of pharmaceutical products investment; and

- (c) the manufacture of pharmaceutical products investment will benefit the economic development of Fiji.

(3) When considering an application for a manufacture of pharmaceutical products investment package under subregulation (1), the Minister or CEO, as applicable, must take into account the following matters—

- (a) the assets and liabilities of the company;
- (b) the nature and extent of the manufacture of pharmaceutical products investment;
- (c) whether the company is approved by the Fiji Pharmacy Board;
- (d) such other matters as the Minister or CEO may consider relevant to the desirability or otherwise of the manufacture of pharmaceutical products investment for Fiji and the capability of the company to complete it.

(4) The decision of the Minister or the CEO, as applicable, under this regulation is final.

(5) Notwithstanding subregulation (4), a person whose application (including partial rejected application) has been rejected may make a new application or amend and resubmit the original application.

Application for the manufacture of pharmaceutical products investment

7.—(1) A company (“applicant”) may, in writing, apply to the CEO for provisional approval to carry out a manufacture of pharmaceutical products investment, setting out the following—

- (a) the name and registered office of the company;
- (b) the names of all directors and shareholders of the company together, including shareholdings of the directors and shareholders;
- (c) a recent statement of all assets and liabilities of the company;
- (d) evidence of the company’s ability to complete the manufacture of pharmaceutical products investment; and
- (e) estimates of the projected income from the new pharmaceutical manufacturing business.

(2) The CEO may—

- (a) require the applicant to provide other information he or she may consider necessary in relation to the application; or
- (b) prescribe particular requirements applicable to any particular area of Fiji on the manufacture of pharmaceutical products investment.

Effect of provisional approval

8.—(1) When a provisional approval is granted, all exempt goods, imported within the period specified in the definition of “manufacture of pharmaceutical products investment” under regulation 3, by or on behalf of the company and used in the carrying out of the manufacture of pharmaceutical products investment, are exempt from all duties payable in respect of their importation.

(2) Before exempt goods are allowed to be imported by a company, it is a condition of importation that the company must first provide proof that such goods cannot be produced locally to the satisfaction of the Minister, who will decide whether such goods are to be imported.

(3) Nothing in this regulation applies to any tax payable under the Value Added Tax Act 1991.

Completion of manufacture of pharmaceutical products investment package

9.—(1) If a company has been granted provisional approval, the company must complete the manufacture of pharmaceutical products investment within 24 months from the date on which the provisional approval was granted.

(2) Subject to the other provisions of this regulation, where a company has been granted provisional approval and has completed the manufacture of pharmaceutical products investment, the company may apply to the Minister for final approval.

(3) An application under subregulation (2) must be made in writing and supported by the following—

- (a) fully audited final accounts showing the total cost of the manufacture of pharmaceutical products investment;
- (b) a completion certificate from the local authority; and
- (c) a final plan showing the site, layout and surrounding area for the manufacturing of pharmaceutical products.

(4) Upon receiving an application under subregulation (2), the Minister may, after consulting with the Minister responsible for health and medical services—

- (a) reject the application; or
- (b) give final approval to the application, with or without any condition.

(5) Subject to regulations 10 and 11, no approval must be granted under this regulation if the Minister is satisfied that the company has failed to complete the manufacture of pharmaceutical products investment or has failed to comply with any condition upon which provisional approval was granted.

(6) If an application for final approval is rejected, the duties exempted under this Part immediately become due and payable by the company.

(7) The Minister must, in writing, notify the following persons of the decision to reject or grant the application—

- (a) the applicant;
- (b) the Minister responsible for health and medical services; and
- (c) the CEO.

Extension of time for completion

10.—(1) If a company to which provisional approval has been granted is unable to complete its manufacture or pharmaceutical products investment within the period specified

in the definition of “manufacture of pharmaceutical products investment” in regulation 3 due to unforeseen circumstances or some other act beyond the control of the company, the company may apply in writing to the Minister to extend the time by which the manufacture of pharmaceutical products investment must be completed.

(2) If the Minister extends the time under subregulation (1), the company continues to enjoy the duty free concession provided for by regulation 8 during the extended period.

Final approval if completed

11. An application for final approval shall not be granted unless—

- (a) the Minister, after consulting the Minister responsible for health and medical services, is satisfied that the company has in all respects completed the requirements of a manufacture of pharmaceutical products investment; and
- (b) the factory for the manufacture of pharmaceutical products is fully operational.

Effect of final approval

12. Notwithstanding anything contained in these Regulations, if the Minister gives final approval to the application, the income of a person derived from a new or existing activity in manufacturing pharmaceutical products as approved by the CEO from 1 August 2019 is exempt income as follows—

- (a) in the case of a capital investment from \$250,000 to \$1,000,000, for a period of 5 consecutive tax years;
- (b) in the case of a capital investment from \$1,000,001 to \$2,000,000, for a period of 7 consecutive tax years; and
- (c) in the case of a capital investment of more than \$2,000,000, for a period of 13 consecutive tax years.

Revocation of manufacture of pharmaceutical products investment package

13. The Minister may revoke any manufacture of pharmaceutical products investment package if the company or owner has—

- (a) breached any condition of provisional or final approval;
- (b) failed to comply with any of the requirements of these Regulations; or
- (c) been convicted of an offence under these Regulations or any other written law relating to taxation, customs or excise.

Made this 31st day of July 2019.

A. SAYED-KHAIYUM
Attorney-General and Minister for Economy