We have never been subject to any lawsuit against us in relation to environmental law violations (in the past and at present). However, we cannot predict the impact that unforeseeable environmental contingencies or new or amended laws, rules or regulations may have on us or our production facilities.

## 1.4 Regulations related to our Business Operations

### 1.4.1 Regulatory framework in respect to the manufacturing and sale of our products

#### 1.4.1.1 Overview

As a developer, manufacturer, marketer and distributor of pharmaceutical and consumer health products, we are subject to regulation and oversight from regulatory authorities in the markets in which we are present. Our products are treated either as food or drug products, the manufacture and sale of which requires both registration and licensing by government agencies in each of the countries in which we operate.We had obtained all necessary licenses, registrations and permits to manufacture and sell our nutraceutical, prescription pharmaceutical and OTC products of our Mega We Care™ branded products business. In addition, our Maxxcare™ distribution business had obtained all necessary licenses, registrations and permits to sell and distribute ournutraceutical, prescription pharmaceutical, and OTC products, as well as FMCG products for both our Mega We Care™ branded products business and our principals.

#### 1.4.1.2 Good Manufacturing Practice

GMP is a set of principles, requirements and procedures for manufacturing pharmaceutical products to ensure the quality necessary for human consumption. GMP covers quality management and control, requirements regarding personnel, premises and equipment, documentation, product manufacturing, contracts for product manufacturing and analysis, storage practices, reclamation, product withdrawal and self-monitoring. A basic underlying premise of GMP is that quality cannot be tested in the finished batch of production but must be built into all stages of the pharmaceutical manufacturing process. Most markets in which we operate require us to comply with GMP standards set by local regulators.

#### 1.4.1.3 ASEAN harmonization of pharmaceutical registration

Our Southeast Asian markets contributed 87.7% of our total sales for the year ended December 31, 2020. Within Southeast Asia, our Key Markets, comprising markets in Thailand, Myanmar, Vietnam, contributed 74.4% of our total sales for the year ended December 31, 2020. Thailand, Vietnam and Myanmar, along with Singapore, Malaysia, Philippines, Indonesia, Cambodia, Brunei and Laos, are members of ASEAN. ASEAN was established to promote regional economic unity and cooperation, and aims to create a free trade area and a single market by 2015.

Part of the ASEAN trade initiative includes a public health and pharmaceutical harmonization scheme, which includes developing harmonized guidelines for the regulation of pharmaceuticals and a unified format of drug registration applications, the ASEAN Common Technical Dossier ("ACTD"). For this purpose, an ASEAN Common Technical Requirements was also prepared and approved by the group countries to serve as a foundation for ACTD.

Thailand was among the first group of countries to implement the ACTD, which it implemented in 2009 by virtue of the Notification of the Thai FDA regarding the Complete Implementation of ASEAN Harmonized Products on Pharmaceutical Registration dated 2 November 2007 . There are 4 parts to ACTD application: Part I – Administrative Documents; Part II – Quality Documents; Part III – Pre-clinical Documents; and Part IV – Clinical Documents. Part I is comprised of three sections, which respectively provide (i) an introduction to the product; (ii) an overview of the contents of the whole dossier; and (iii) a prescribed application form to which relevant certificates and approvals are provided. Part II contains three sections which address the quality of the product, the manner in which it is manufactured, and any studies in relation to the product. As Part III and IV are relevant only to new prescription pharmaceutical products (i.e. not generic, off-patent products), these parts do not apply to our products which are under development.

We believe the proposed ASEAN public health and pharmaceutical harmonization scheme represents a future opportunity for us to further improve the speed, efficiency and cost effectiveness of its new product development and registration initiatives within Southeast Asia and will enable us to more effectively leverage our product portfolio across all Southeast Asian markets.

Although the ACTD guidelines are uniform throughout ASEAN, the interpretation of the guidelines remains country-specific. This has led to variations in the content of the ACTD applications from country to country.

The following sections outline the key laws and regulations we are subject to in our Key Markets and Australia and approvals obtained in other jurisdictions, including the implementation of the ACTD in each of our key Southeast Asian markets.

## 1.4.2 Regulatory Regime in Thailand

All drugs and foods sold in Thailand are regulated by the Thai FDA, which is administered by the Ministry of Public Health.

The following are the key laws and regulations to which our operation are subject to in Thailand.

### 1.4.2.1 Drugs Act B.E. 2510 (as amended) (the "Drugs Act")

The Drugs Act regulates all "drugs", as defined within the Drugs Act. The definition of "drugs" includes (i) substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal illness, (ii) pharmaceutical chemical substances or semi-processed pharmaceutical substances, (iii) substances intended to produce an effect on health, structure or any functions of a human or animal body, and (iv) substances notified by the Ministry of Public Health, but excludes any edible item categorized as food.

Our OTC and prescription pharmaceutical products and many of our nutraceutical products fall within the definition of "drugs" under the Drugs Act.

The Thai FDA, through the Drug Commission, is the main regulatory body responsible for the administration of the Drugs Act.

The key regulations which apply to our OTC and prescription pharmaceutical products and those nutraceutical products that are classified as drugs are described below.

1. **Licensing, manufacturing and importation**

Drug manufacturers must hold four licenses, namely (i) a conventional drug import license, (ii) a conventional drug production license, (iii) a traditional drug import license, and (iv) a traditional drug production license.

In order to obtain a conventional or traditional drug production license, a drug manufacturer must submit its manufacturing plant's layouts for Thai FDA's approval. The Thai FDA will then inspect the plant, and, if the plant meets the Thai FDA's requirements, a drug production license will be issued. Once issued, the drug production license must be renewed annually.

As for the conventional or traditional drug import license, the Thai FDA will inspect the drug storage premises of the manufacturer to ensure that the storage premises meet sanitary, air ventilation and safety requirements so as to maintain the quality of drugs. Once issued, the drug import license must also be renewed annually.

We have duly obtained all necessary drug production licenses and drug import licenses from the Thai FDA in respect of conventional and traditional drugs.

The Notifications of the Ministry of Public Health issued under the Drugs Act regarding the details of the measures and procedures for drug manufacturing require that drug manufacturing facilities comply with the relevant GMP guidelines in order to ensure that the drug and its manufacture meet standards of quality, efficacy and safety. Our Thailand manufacturing facilities have obtained certificates and comply with the terms of GMP guidelines.

**2. Registration and Categories of Drugs**

In addition to the above licensing requirements, drug formulations must be registered with the Thai FDA by drug manufacturers or importers prior to the manufacturing or import of such drug. After a drug import license or a drug production license has been obtained (whether for a conventional or traditional drug), the formulation of the drug is lodged with the Thai FDA for registration. Once a registration certificate for the drug has been issued, the drug may be produced or imported, as the case may be.

There are six categories of drugs with differing registration requirements: (i) generic drugs, (ii) new drugs, (iii) new generic drugs, (iv) narcotic drugs, (v) biological drugs and (vi) traditional drugs. The registration requirements for these different drugs categoriescanbe summarized as follows:

(i) Generic drugs are those products which were registered prior to 1989.

(ii) New drugs are those products which are submitted for registration after 1989.

(iii) New generic drugs are new versions of generic drugs.

(iv) Narcotic drugs

(v) Biological drugs are new biological products or conventional biological products.

(vi) Traditional drugs are herbal medicines and modified herbal medicines.

From our experience, registration of drug formulations generally requires 12 to 18 months from the time of initial application.

We hold registrations for all of the products we sell in Thailand, as required by law.

**3. Inspection**

The Thai FDA regularly conducts inspections of drugs factories, and requires drugs to be submitted for laboratory testing. In the event of any violation of the requirements of the Drugs Act, the manufacturer may be subject to prosecution or be required to conduct a product recall.

**4. Labelling and advertising**

In addition to licensing requirements and formulation registration as stated above, drugs in Thailand are also subject to labelling and advertising requirements. For instance, some drugs must be accompanied by usage instructions and warning statements on the drug label. In addition, any form of advertisement must be approved by Thai FDA.

**1.4.2.2 Food Act B.E. 2552 (as amended) (the "Food Act")**

The Food Act regulates all edible "food" substances, as defined within that Food Act. The definition of "food" within the Food Act includes any edible item, but excludes any edible item which is categorised as a drug or medicine in other legislation (such as the abovementioned Drugs Act).

The Thai FDA, through the Food Commission, is the main regulatory body responsible for the administration of the Food Act.

Some of the Company's nutraceutical products described in section 3.1.1, fall within the Food Act definition of "food". As such, our import, manufacture, and marketing of some of our nutraceutical products is regulated under the Food Act.

The Food Act establishes a Recommended Dietary Intake ("RDI") chart, containing recommended daily consumption standards for vitamins, minerals and/or other ingredients. In addition, the Notification of Ministry of Public Health No.293 regarding Nutraceutical Products stipulates that vitamin and mineral content of nutraceutical products shall not exceed the maximum content specified in nutrient lists for RDI. In other words, if the vitamin and mineral content of any nutraceutical product exceeds the relevant RDI threshold, such nutraceutical products shall be regarded as "drugs" under the Drugs Act.

The key regulations which apply to some of our nutraceutical products are described below.

**1. Licensing, manufacturing and labelling**

Food manufacturers regulated under the Food Act must obtain two licenses prior to the commencement of its business activities, namely, (i) a food production license and (ii) a food import license.

In order to obtain a food production license, a food manufacturer must submit its manufacturing plant's layouts for Thai FDA approval. The Thai FDA will then inspect the plant, and, if the plant meets the Thai FDA's requirements, a food production license will be issued. Once issued, the food production license must be renewed every three years.

As for the food import license, the importer must submit its food storage premise's layout for Thai FDA approval. In this respect, the Thai FDA shall determine whether or not the storage premise has complied with sanitary, air ventilation, and safety requirements. In addition, there must be sufficient equipment for the storage and preservation of food. Once the food import license has been issued, it must be renewed every three years.

In addition, certain food products prescribed by the Thai FDA must be registered with the Thai FDA prior to their import for sale in Thailand. The imported food products are generally required to have standard labels affixed. Nutrition labelling is also required for certain products. According to the regulations issued by the Ministry of Public Health, the manufacture of specified classes of foods must also comply with GMP standards.

We have complied with the foregoing requirements and have duly obtained a GMP certificate which certifies that our manufacturing facilities conform to the Code of Practice issued by the Ministry of Public Health. This Code of Practice, which specifies general principles of food hygiene, was issued in accordance with international standards for the manufacture of food supplements.

**2. Registration and categories of foods**

The registration of foods in Thailand fall into 4 categories, comprised of:

(i) Specially Controlled Foods are foods which require product registration. The production of specially controlled foods must comply with quality standards, specifications, packaging, and labelling requirements, as well as other aspects of good manufacturing practices. Examples of such foods are infant foods and weight control foods.

(ii) Standardized Foods are foods whose quality and labelling must comply with the standard requirements, but for which registration is not required. Foods in this category are mainly locally-produced food from small-scale or household industries.

(iii) Labelled Foods are foods which expose a lower risk of hazard to consumers' health. The regulation of such foods mainly focus on the labelling of the foods in order to avoid consumers being misled (i.e. irradiated foods, chewing gum, candy, bread and sauces in sealed containers).

(iv) General Foods are foods which are not listed in the categories above. As this includes raw food, cooked food, preserved or non-preserved food, registrations are not required. Nevertheless, the production of general foods is controlled and monitored for hygiene, safety, labelling and advertisement.

Only specially controlled foods require production registration before their production or import. The registration of specially controlled foods generally takes 3 to 6 months from the time of the initial application, in cases where the product contains an ingredient which has been registered before. In other cases, registration may take up to 18 months.

**3. Inspection**

The Thai FDA regularly conducts the inspection of food factories and premises, and subjects food products for laboratory testing. In the event of violations, product recall and/or prosecution may be carried out.

**4. Labelling and advertising**

In addition to licensing, manufacture and import control, foods in Thailand are subject to labelling requirements. Any products which (i) have nutritional or health claims, (ii) target specified consumer groups in sale promotions, or (iii) which have been subject to Thai FDA notification as requiring nutritional labelling, must bear standardized nutritional labels. In addition, any form of advertisement through any public medium is subject to approval from the Thai FDA.

**1.4.2.3 Price of Goods and Services Act B.E. 2542 (the "Price Control Act")**

The Price Control Act regulates the distribution prices of the controlled goods or services. The Central Price of Goods and Services Committee (the "CPS Committee") has authority to determine the maximum sale or distribution prices of the controlled goods or services, and may require for the declaration of the amount, place of storage, costs, expenses, production plan, distribution plan and the methods for distribution of the controlled goods or services.

In general, types of the controlled goods and services shall be annually prescribed by the Notification of the CPS Committee, which currently include, among others, (i) product contain oil or fat from plants and animals, (ii) drugs, and (iii) products in sealed containers. In addition, upon the products being prescribed as controlled goods, the CPS Committee shall have further discretion to determine the pricing control mechanism of such products within the aforesaid scope of its authority.

As a consequence, the pricing of certain of our products which are subject to the price control of the CPS Committee may not be discretionarily increased. As of December 31, 2014, the Company has not been materially affected by such controls.

**1.4.2.4 Public Health Act B.E. 2535 ("Public Health Act")**

The Public Health Act regulates the activities and operations which may be harmful to "public health", as defined under the relevant Ministerial Regulations. The production of certain kinds of food and drugs which are deemed to be harmful to public health requires a license from the local authority in the area that the factory is located ("Public Health License"). We, as a prescription pharmaceutical, OTC and nutraceutical products manufacturer, are required to comply with the Public Health Act.

Applications for Public Health License must be sent to the local authority, which then examines the application to ensure that certain conditions regarding sanitation and other standards are met.

All licenses issued under the Public Health Act are valid for one year from the date of issuance. Upon receipt of the application, business operations may continue unless an order is issued from local officials to cease operations. Local regulations govern the rules, procedures and conditions for the application to renew the license. We currently hold such a license.

Section 65 of the Public Health Act prescribes penalties for non-compliance with the provisions of the said act. If the relevant fees for the operations of the business are not paid a fine at a rate of 20% of the outstanding amount in fees shall be added to the overdue amount. If the such fees and their outstanding amounts have not been paid or are overdue for more than two periods, the local official may order the business operation of the defaulting business operator to cease until such outstanding fees have been paid in full.

**1.4.2.5 Investment Promotion Act B.E. 2520 (the "Investment Promotion Act")**

The Investment Promotion Act provides tax and other economic incentives to Thai and foreign companies in order to stimulate investment in Thailand.

The Investment Promotion Act is chiefly administered by the BOI. In general, the BOI will promote and grant BOI certificates for projects that will stimulate the Thai economy (or specified areas thereof), create employment, reduce environmental impacts and develop Thailand's infrastructure. The BOI is also empowered to grant a wide range of fiscal and non-fiscal incentives. The investment incentives that the BOI grants to a particular project, and the period for which those incentives will subsist, are specified in a BOI certificate.

We have received the privileges by the Board of Investment under the provisions of the Industrial Investment Promotion Act of B.E. 2520 relating to manufacturing of medicines starting from 1 May 2018. The privileges granted include exemption from payment of import duty on machinery approved by the Board and exemption from payment of income tax for certain operations for a period of eight years from the date on which the income is first derived from such operations.

The investment privileges granted to us contained in our BOI certificate are as follows:

(i) exemption from import duties on machinery until the opening of project for which this exemption is given subject to extensions of time limit by BOI ;

(ii) exemption from import duties on the raw materials and components for the manufacturing of the products for export;

(iii) exemption from corporate income taxes (tax holiday) for 8 years from the date on which the income is first derived from such operations;

(iv) exclusion from taxable income in the hands of shareholder of dividends declared by the company out of exempted profits.

The Company and a subsidiary in Thailand have been granted privileges by Revenue Department under the Revenue Code Governing Reduction of Tax Rates and Exemption of Taxes (No. 587) B.E. 2558 relating to their status as International Trade Centre. The privileges granted include an exemption from payment of income tax for certain transactions for a period of fifteen years commencing from 1 January 2017. As promoted companies, the Company and its subsidiary must comply with certain terms and conditions applicable to International Trade Centre. The Royal Decrees cancelled benefits of International Trade Centre effective from 1 June 2019.

The Company has been granted privileges by Revenue Department under the Revenue Code Governing Reduction of Tax Rates and Exemption of Taxes (No. 674) B.E. 2561 relating to its status as International Business Center. The privileges granted include an exemption from payment of income tax for certain transactions for a period of fourteen years and six months commencing from 1 June 2019. As a promoted company, the Company must comply with certain conditions applicable to International Business Company

### 1.4.3 Regulatory Regime in Vietnam

The following are the key laws and regulations to which our Vietnam operations are subject.

**1. Licensing**

Mega Lifesciences Vietnam Limited ("Mega Vietnam") requires, and holds (save for those that are pending approval), the following licenses or authorizations to conduct its operations:

| License/authorisation | Purpose of license/authorisation | Date of approval | Expiry |
|---|---|---|---|
| Investment certificate | Authority to trade. | July 3, 2000 | July 3, 2020 |
| Certificate of eligible facilities for food safety | Required for any business engaged in food trading. | Submitted, but not yet approved | n/a |
| Certificate of announcement on conformity with regulations on food safety | Required for each food product traded by Mega Vietnam. | Mega Vietnam has a certificate for each food product in which it trades. The relevant approval date varies for each food product. | Varies for each food product. |
| Certificate of good storage practices | Required for operation of Ho Chi Minh City warehouse. | March 24, 2015 | March 23, 2018 |
| Certificate of satisfaction of drug trading conditions | Required for storage of drugs at Ho Chi Minh City warehouse. | July 11, 2016 | Perpetual |

**2. Import controls**

Vietnamese law provides that a foreign company (such as Mega Lifesciences Public Company Limited and Mega Lifesciences Pty Limited) cannot export its pharmaceutical products directly into Vietnam.

In order to export drugs indirectly from abroad, the foreign company must obtain a license for "operation in medicine and pharmaceutical materials in Vietnam" ("Foreign Vietnamese Pharmaceutical License") from the DAV and then conduct the export of drugs into Vietnam through a duly licensed Vietnamese entity. Mega Lifesciences Public Company Limited and Mega Lifesciences Pty Limited each hold a Foreign Vietnamese Pharmaceutical License. These such licenses expire on May 16, 2018. These licenses permit Mega Lifesciences Public Company Limited and Mega Lifesciences Pty Limited to export functional foods, certain pharmaceutical products and medical devices (i.e. alternative medicines and herbs) into Vietnam through a duly licensed Vietnamese entity, such as Mega Vietnam.

**3. Price controls**

In Vietnam, the prices of pharmaceutical products in Vietnam are managed in accordance with the following principles:

(i) entities engaging in pharmaceutical products business (including manufacturers, exporters, importers, wholesalers, retailers etc) can set prices for pharmaceutical products but subject to the 'inspection' and 'control' by the relevant Government agency; and

(ii) the relevant Government agency may apply measures to stabilize drug prices.

Joint Circular 50/2011/TTLT-BYT-BTC-BCT issued by the Ministry of Health, the Ministry of Finance and the Ministry of Industry and Trade dated December 30, 2011 on the management of drug prices ("Circular 50") provides for 'inspection' and 'control' measures which may be exercised by the relevant Government agency, which include:

(i) The requirement that regulated entities declare prices of pharmaceutical products (including, import price, wholesale and retail prices) prior to the first circulation to the market of such products. If the regulated entity seeks to change the price of the relevant product, the declaration must be renewed.

(ii) Wholesalers and retailers must list the prices by way of public notices on boards, papers or other means placed, hung or stuck at sale places convenient for customers' observation. Prescription products must not be sold at a higher price than the displayed price.

Circular 50 also provides for the procedures for declaring the prices of drugs imported from foreign countries or manufactured domestically. The procedures for declaring the prices of drugs manufactured outside of Vietnam are as follows:

(i) The price of a product must be declared following its registration and prior to the product being first circulated. Any change to the declared price requires the price declaration to be renewed.

(ii) The price declaration dossier must be made in the form prescribed in Circular 50. The price declaration dossier will be made in two sets, one set is submitted to the DAV and the other is for filing.

(iii) The price declaration renewal dossier will be made in two sets, one of which is submitted to the DAV and the other is for filing. The dossier will consist of (i) request letter for a price declaration renewal in the form prescribed in Circular 50 and (ii) list of price declaration renewal in the form prescribed in Circular 50.

(iv) Upon receipt of a proper price declaration dossier, the DAV will issue an acknowledgement of receipt of price declaration renewal dossier.

Although no approval from the DAV is required in respect of the declared price, the relevant Government agency has the right to refuse to accept the price declaration or declaration renewal if the price is 'unreasonable'. The 'reasonableness' of pricing is determined on the basis of (i) import costs, total production costs, circulation costs, (ii) prices in domestic and international markets, and (iii) changes in input costs such as materials, exchange rates and other costs. In the event of refusal of a declared price, the relevant Government agency will send an official notice to the declarant requesting the declarant to reconsider its declared price.

The relevant Government agency may apply measures to stabilize drug prices on the market. However, regulations on pharmaceutical products are silent on what potential such stabilization measures are.

**4. ACTD Registration**

In Vietnam, Parts I and II of the ACTD dossier must be submitted for the registration of prescription pharmaceutical products and OTC products.

Subject to some exceptions, there are 12 prescribed active pharmaceutical ingredients ("APIs") contained in generic products for which a bioequivalence study must be submitted with the ACTD dossier. Product registrations featuring APIs that are known to be affected by food may be required to provide a bioequivalent study on a case by case basis.

In addition, those products that feature a sustained, modified or extended release delivery profile require the submission of a bioequivalence study, irrespective of the API contained within the product.

For the registration of herbal and traditional drugs, Parts I and II of the ACTD dossier must be submitted. However, Part II is modified in the case of such registrations to provide further information on the ingredient herbs and/or plants, its analysis of markers, and safety and efficacy compared to chemical drugs. A bioequivalence study is not required.

ACTD registration in Vietnam takes approximately 12 to 18 months. Registrations are valid for a maximum duration of 5 years. Re-registration of the relevant product must be submitted 6 months prior to its current registration's expiry, otherwise the product will subject to a new ACTD registration process.

The Vietnamese Ministry of Health may also request samples of a product for testing on a case by case basis. However, in practice, the rate of registrations subject to such testing is very low.

**5. Functional food registration**

In Vietnam, our nutraceutical products are classified as functional foods. As such, they must be registered with the Food Administration Department. Registration of such products takes between 2 to 8 weeks of the filing of the product application. Registrations are valid 3 to 5 years (with 5 years being possible in the case of businesses which have ISO 22000, HACCP or similar accreditation).

### 1.4.4 Regulatory Regime in Myanmar

The following are the key laws and regulations to which our operations are subject to in Myanmar.

**1. Licensing**

In Myanmar, Mega Lifesciences Limited ("Mega Myanmar") and the representative office of Mega Lifesciences Pty Limited (Thailand) are required to hold, and do hold, the following licenses or authorisations to conduct their operations:

| License/authorisation | Purpose of license/ authorisation | Date of approval | Expiry |
|---|---|---|---|
| Permit to Trade No. 137/1995 issued by the Directorate of Investment and Companies Administration to Mega Myanmar | Authority to trade. | October 30, 2014 | October 29, 2019 |
| Permit to Trade No. 010/2003 issued by the Directorate of Investment and Companies Administration to Mega Lifesciences Pty Limited (Thailand) | Authority to trade. | November 21, 2014 | November 20, 2019 |

**2. Import controls**

All products which are classified as a food or a drug in accordance with the National Food Law or the National Drug Law (as the case may be) must receive an import recommendation from the Myanmar Food and Drug Administration and receive an import license from the Ministry of Commerce. In our experience, it takes approximately 3 to 4 days to obtain approval of an import license for a food or a drug product (as the case may be). The import license for each food or drug product is valid for 3 to 5 months.

Registered drugs may be imported only by a Myanmar national or a corporation that is a general registered importer. In addition to this, the person or the corporation importing the drugs must have a special registration certificate for pharmaceuticals known as a drug importation approval certificate. Each shipment must also have a separate licence issued by the Ministry of Commerce.

**3. ACTD Registration**

All of our branded products are classified as either a drug or a food under Myanmar law.

A "drug" is defined by Section 2 (b) of the National Drug Law as "a substance for use, whether internal or external, in the diagnosis, prevention and treatment of disease, birth control or for any beneficial effect in human beings and animals". Also included in the definition is any substance determined by notification to be a drug by the Ministry of Health.

"Food" is defined under the National Food Law as being any "edible thing that human beings can readily eat or drink, ingredient included therein or food additives except drug. This expression also includes things determined to be food by the Ministry of Health by notification from time to time."

All products which are classified as drugs in accordance with the above must be registered with the Myanmar Food and Drug Administration in accordance with ACTD requirements. Based on our experience, it takes approximately 12 to 15 months to obtain product registrations for drugs in Myanmar.

At present, the Myanmar Food and Drug Administration does not have a department which specializes in herbal drug registrations, and therefore approval of registrations of such products may take significantly longer (up to several years) than those products that are classified as drugs.

### 1.4.5 Regulatory Regime in Australia

The following are the key laws and regulations to which our operations are subject to in Australia.

**1. Therapeutic Goods Act**

Manufacturers of pharmaceutical products are regulated by the Therapeutic Goods Administration, or TGA, under the Therapeutic Goods Act 1989 (the "TGA Act"). The TGA regulates the quality, safety and efficacy of pharmaceuticals sold in Australia. The TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard, with a goal of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances. Australian manufacturers of all medicines must be licensed under Part 4 of the Act and their manufacturing processes must comply with the principles of GMP.

**2. Registration or Listing**

All therapeutic goods manufactured for sale in Australia must be listed or registered in the Australian Register of Therapeutic Goods ("ARTG"), before they can be sold. Whether a product is listed or registered in the ARTG depends largely on the ingredients, the dosage form of the product and the promotional or therapeutic claims made for the product.

Within the regulatory framework, medicines are classified as either registered or listed. The following higher risk medicines must be registered on the ARTG, which involves individually evaluating the quality, safety and efficacy of the product .

- All prescription medicines.
- Most over-the-counter medicines.
- Some complementary medicines.

Lower risk medicines containing pre-approved, low-risk ingredients and that make limited claims must be listed on the ARTG. The following listed medicines are assessed by the TGA for quality and safety but not efficacy.

- Some over-the-counter medicines.
- Most complementary medicines.

In Australia, medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homoeopathic and certain aromatherapy preparations are referred to as 'complementary medicines' and are regulated as medicines under the TGA Act.

To be a listed medicine on the ARTG, a product:

- can only contain certain low risk ingredients in acceptable amounts that are permitted for use in listed medicines by the TGA;
- must be manufactured in accordance with the principles of GMP;
- can only make indications (for therapeutic use) for health maintenance and health enhancement or certain indications for non-serious and self-limiting conditions; and
- at the time of submitting a listed medicine application to the TGA, the manufacturer or importer must certify that the goods in the application meet all of the legislative requirements of section 26A (Part 3-2, Division 2) of the TGA Act.

Medicines listed on the ARTG are assigned a unique AUST L number, which must be displayed on the medicine label.

The registration process for medicinal listing can be summarized as follows:

Listed medicines are included on the ARTG via a streamlined electronic listing facility. The process for listing products allows for early market access for low risk complementary medicines. The applicant must certify, upon submission of their application to the TGA, that the goods that are the subject of the application meet all the requirements of listing.

It normally takes 4-6 weeks to get an AUST L number after lodging the application in the eBS. Manufacturer or importer of listed medicines which have been approved for sale in Australia have the choice of either requesting a CPP as per the WHO Certification Scheme or a CLP. A CLP is similar in format to a CPP but is not issued under the WHO Certification Scheme On the Quality of Pharmaceutical Products Moving in International Commerce.

**3. Export regulations**

Medicines intended solely for the purpose of export are required to be listed (not registered) on the ARTG before export is commenced.

As a matter of general principle, the Export Unit only certifies documents, as schedules to CPPs or CLPs, that it can verify. Therefore certification is limited to the following documents only:

- formulation details;
- manufacturing details;
- labels for finished products; and
- product information which is the same as that approved by DSEB for a product registered in the ARTG.

Our production facility in Australia enables us to shorten our products' time to market. As the Australian TGA classifies most nutraceuticals as "complementary medicines," it is generally possible to register a nutraceutical product and obtain a CPP or CLP for it in from 8 to 14 weeks. Once the CPP or CLP is obtained, the dossier for the product facilitates registration of the product in certain of our markets.

**4. Inspection**

The TGA performs inspections of Australian manufacturers of therapeutic goods to ensure that they meet an acceptable standard of GMP or comply with QMS standards, as legislated in the TGA Act and TGA Regulations, including the Manufacturing Principles and the Therapeutic Goods Orders.

The TGA Act requires that overseas manufacturers of medicines and other therapeutic goods that are not medical devices, supplied in Australia, meet an acceptable standard of GMP comparable to that required for Australian manufacturers. If acceptable documentary GMP evidence cannot be provided, the TGA will undertake on-site inspections in the same manner as that conducted for the Australian manufacturers.

Australian manufacturers of all types of therapeutic medicines must be licensed under regulations of the TGA Act.

The inspection is conducted by 1-2 inspectors and lasts from 1-5 days. Upon successful completion of the audit, the GMP certificate is granted and is usually valid for 1-3 years depending on the level of compliances observed by the inspectors. No certification extends beyond 3 years. Re-audits are conducted 1-3 months prior to the expiry of the certificate.

Our two plants in Thailand were last audited by the TGA in May 2011. An EU GMP audit was also conducted post the TGA audit and both plants were granted EU certifications until July 2014. Based on the EU certification, the TGA is currently carrying out a desktop audit to potentially extend their certifications until July 2014. Our Australian plant was audited by the TGA in January 2013 and certified until January 2016.

**5. Labelling, packaging and advertising**

Labelling, packaging and advertising of pharmaceutical products are also regulated by the TGA. There are best practice guidelines that are in place for each of these areas, to guide TGA assessors in assessing the appropriateness of the labelling, packaging and advertising of pharmaceuticals. The TGA is responsible for ensuring that therapeutic goods available for sale in Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin pills and band aids, through to goods used to treat serious conditions, such as controlled medicines, vaccines, blood products and surgical implants.

### 1.4.6 GMP Certifications

In addition to its Thai GMP certification, the Company has received the following GMP certificates:

**STATUS OF GMP APPROVALS**

| Country | Authority | Site | Year of first approval | Current status |
|---|---|---|---|---|
| Thailand | Thai FDA | Soi 6 Facility | 1985 | Approved |
| | Thai FDA | Soi 8 Facility | 2009 | Approved |
| Australia | TGA | Soi 6 Facility | 1993 | Approved |
| | TGA | Soi 8 Facility | 2009 | Approved |
| | TGA | Pakenham Facility | 2013 | Approved |
| European Union | German Health Authority | Soi 6 Facility | 2001 | Approved |
| | German Health Authority | Soi 8 Facility | 2008 | Approved |
| Oman | Ministry of Health | Soi 6 Facility | 2009 | Approved |
| Uganda | National Drug Authority | Soi 6 Facility | 2004 | Approved |
| | National Drug Authority | Soi 8 Facility | 2013 | Approved |
| Yemen | Ministry of Health | Soi 6 Facility | 2006 | Approved |
| | Ministry of Health | Soi 8 Facility | 2012 | Approved |
| United Arab Emirates | Ministry of Health | Soi 6 Facility & Pakenham Facility | 2008 | Approved |
| | Ministry of Health | Soi 8 Facility | 2013 | Approved |
| Sudan | Ministry of Health | Soi 6 Facility | 2012 | Approved |
| Ukraine | Ministry of Health | Soi 6 Facility | 2006 | Approved |
| | Ministry of Health | Soi 8 Facility | 2010 | Approved |
| Ethiopia | Drug Administration & Control Authority | Soi 6 Facility & Soi 8 Facility | 2010 | Approved |
| Peru | Ministry of Health | Soi 6 Facility &Soi 8 Facility | 2012 | Approved |