



Australian Government
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Australia
UNLIMITED

COMPLEMENTARY MEDICINES IN CHINA

A guide for Australian business



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INTRODUCTION

This guide has been developed to assist Australian companies interested in exploring the rapidly growing and evolving market in China for complementary medicines and nutritional supplements. It provides an overview of the drivers of demand, key channels of distribution and the regulatory environment that applies to these products, along with practical information about doing business in China.

Austrade would like to acknowledge the assistance of King & Wood Mallesons China in the preparation of this publication, particularly the information on regulatory requirements.

Chinese consumers' demand for complementary medicines and health foods – driven by factors like population ageing, limited availability of primary healthcare, increased disposable incomes and concerns about food safety and environmental pollution – has been well publicised in recent years.

The boom in e-commerce and personal shopper ('daigou') channels for complementary medicines have also attracted widespread interest.

Australia is well placed to respond to this market opportunity and position itself as a trusted source of complementary medicine products thanks to its 'clean, green and safe' reputation, underpinned by robust regulatory systems for food and medicines.

While the potential business opportunities are huge in Australian terms, the regulatory environment in China for complementary medicines and nutritional supplements is significantly different from Australia's and has undergone a number of important changes recently. Professional advice is strongly recommended for any company looking to export these products to China.

This guide is designed as a starting point for Australian companies considering entering the Chinese complementary medicines market. The China Food and Drug Administration regularly reviews and amends regulations pertaining to complementary medicines. Austrade will monitor regulatory developments and periodically update exporters on any major changes.

Austrade can provide Australian companies with market guidance and access to information and referrals. More information, resources and contacts are available at austrade.gov.au.

We wish you every success on your export journey.



EXECUTIVE SUMMARY

The demand for complementary medicines is growing rapidly in China as an increasingly health-conscious population searches for products that enhance their wellbeing.

The Chinese health food market – which includes vitamins, dietary supplements and minerals, animal and herbal extracts, and traditional Chinese medicine (TCM) – is currently valued at RMB200 billion (US\$30 billion) and is projected to grow by 10 per cent every year until 2025. The Boston Consulting Group forecasts that China's overall health and wellbeing market could be worth over RMB400 billion (US\$60 billion) by 2020.¹

The growing market for complementary medicines has been driven by a heightened awareness of health, wellness and safety issues among Chinese consumers. A large ageing population is seeking to manage specific conditions while younger consumers, particularly women, want to maintain their health. Many prefer international brands and have the income to pay for foreign-made products.

The Chinese Government has also made health a priority in its 13th Five-Year Plan (2016–2020), with a suite of national initiatives that support demand for complementary medicines. This includes promoting the development of TCM by building research institutions and standardising TCM products and services.

A market with wide-ranging needs

Despite there being over 15,000 registered health foods in the Chinese market, there is still great potential for more, as consumers receive better healthcare advice and become more sophisticated in their consumption. There is high demand for health foods with functional claims, and nutritional supplements (vitamins and mineral products). Other growth areas include over-the-counter medicines, food for special medical purpose and sports supplements.

While there is demand for all forms of complementary medicines, the opportunities for products based on TCM principles are among the highest, due to strong interest and trust in TCM among Chinese consumers. Another area of opportunity is supplying herbs and other ingredients to Chinese pharmaceutical companies looking to source uncontaminated raw materials.

Be informed and prepared

Australian exporters should be mindful that the Chinese complementary medicines market is increasingly regulated. While the Chinese Government has assisted exporters by streamlining the registration process for health products, it has also introduced various policies to protect consumers' rights and reviewed regulations on cross-border e-commerce. The latter may have considerable implications for Australian business as online channels are a popular and effective way of selling to China's tech-savvy population.

This guide includes sections on navigating the regulatory environment for complementary medicines, including registration and filing for different product categories; the pros and cons of various export channels; and common risks and pitfalls that exporters can avoid with thorough preparation.

Seizing the opportunity

The Australian complementary medicines sector is well positioned to compete for emerging market opportunities. Australian vitamins, minerals, supplements and health products are highly regarded in China for being 'clean, green and safe'. Australia's strong regulatory frameworks are well known and its complementary medicines research is well respected. These favourable attributes put Australian businesses in a prime position to capitalise on China's rising demand for high-quality complementary medicines.



US\$30bn

CURRENT VALUE OF CHINESE
HEALTH FOOD MARKET



15,000

HEALTH FOODS REGISTERED
WITH POTENTIAL FOR MORE



US\$60bn

PROJECTED VALUE OF CHINESE
WELLBEING MARKET BY 2020

OVERVIEW

The complementary medicines market in China is booming, driven by rising incomes and consumer spending, greater interest in health and wellbeing, and regulatory reforms.

The China Healthcare Association Health Food Market Working Committee currently values the health food market in China at RMB200 billion (US\$30 billion). It forecasts that the market will grow 10 per cent year-on-year between 2015 and 2025 and estimates consumers' purchasing power for health foods can potentially reach RMB1 trillion (US\$150 billion).^{2,3}

According to the China Chamber of Commerce for Import & Export of Medicines & Health Products, imports of health foods and nutritional supplements (including ingredients and finished products) into China were worth US\$2.67 billion in 2014.

The top five source markets for complementary medicines are: the US (US\$240 million), the Netherlands (US\$110 million), Thailand (US\$83 million), Germany (US\$81 million) and Taiwan (US\$68 million). Imported products are mainly vitamins, fish oil, protein powder, functional drinks and formula nutritional foods.⁴

Market drivers

A number of demographic, social and policy factors are driving the demand for complementary medicines in China.

Rising incomes and consumer spending

The rapid expansion of China's middle class population in both rural and urban areas has been well documented. A 2013 McKinsey report estimated that by 2022, more than 75 per cent of China's urban consumers will earn RMB60,000 to RMB229,000 (US\$9,000 to US\$34,400) annually.⁶

With increased consumer income and overall consumption comes higher spending on health. In 2015, average disposable income was RMB21,966 (US\$3,293), an 8.9 per cent increase from 2014. Average spending on health-related products and services was RMB1,165 (US\$175), equivalent to 7.4 per cent of total spending.⁷

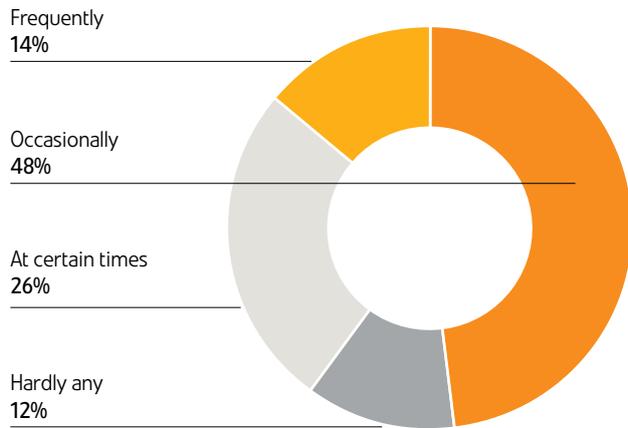
A 2016 survey of 12,430 consumers by the China Consumers' Association found 58 per cent of interviewees reported purchasing health foods. The survey also examined frequency of consumption, monthly expenditure on health foods and attitudes towards domestic and imported products, as shown in Figures 1, 2 and 3.⁸

Table 1: China's exports and imports of health foods and nutritional supplements in 2014⁵

CATEGORY	EXPORT		IMPORT	
	Quantity (tonnes)	Value (US\$ million)	Quantity (tonnes)	Value (US\$ million)
Vitamins	223,362	1,970	14,865	240
Amino acids	819,422	1,570	165,212	610
Plant extracts	67,839	1,780	22,453	310
Chondroitin sulphate	4,445	310	121	1
Coenzyme and Q10	87,680	510	14,593	230
Fish oil	29,327	130	46,407	100
Royal jelly/honey/wax	13,554	110	123	2
Finished products	357,026	1,180	123,627	1,180
TOTAL	1,602,655	7,560	387,401	2,673

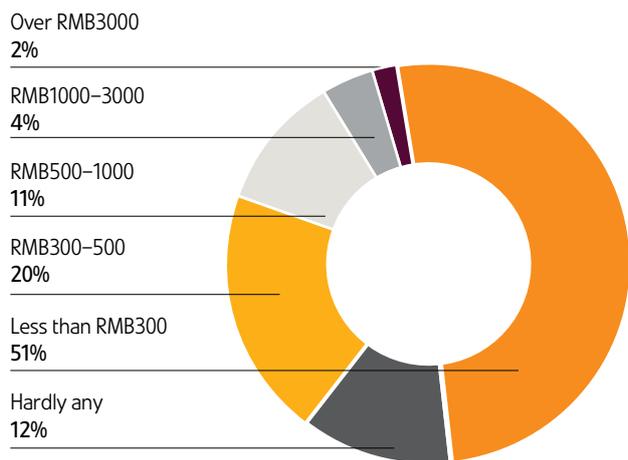
Source: The China Chamber of Commerce for Import & Export of Medicines & Health Products, Situation and Outlook of China's Imports and Exports of Nutritional Supplements and Health Foods, March 2016

Figure 1: Frequency of health food consumption



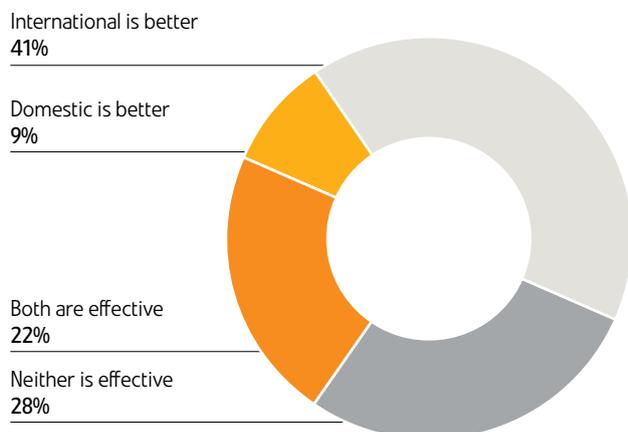
Source: China Consumers' Association, Report on Health Food Consumer Awareness Questionnaire, June 2016

Figure 2: Monthly expenditure on health foods by purchasers



Source: China Consumers' Association, Report on Health Food Consumer Awareness Questionnaire, June 2016

Figure 3: Consumers' appraisal of the effectiveness of domestic and international health foods



Source: China Consumers' Association, Report on Health Food Consumer Awareness Questionnaire, June 2016



14.3%

AUSTRALIA'S SHARE OF CHINESE COMPLEMENTARY MEDICINES MARKET



us\$175

AVERAGE SPENDING ON HEALTH-RELATED PRODUCTS AND SERVICES



us\$150bn

CONSUMERS' ESTIMATED PURCHASING POWER FOR HEALTH FOODS



13%

POPULATION AGED 65 AND OVER BY 2020

Ageing population

Improved life expectancy and the 30-year impact of the one-child policy on population distribution mean that China's population is ageing rapidly. The proportion of the population aged 65 and over has grown from 8.5 per cent in 2009 to 10.5 per cent in 2015 and is projected to reach 13 per cent by 2020.^{9,10}

This ageing population, along with rising rates of chronic disease, is creating a growing cohort of older consumers looking to maintain their health and independence while managing one or more health conditions. Health food products for the middle aged and elderly are thought to account for about half of the Chinese health food market.

Changing family planning policy

After 30 years of the one-child policy, the Chinese Government revised its family planning policy in 2015, allowing each eligible couple to have two children. It has been estimated that 60 per cent of these 11 million eligible couples will have another baby in the next four to five years, resulting in one to two million additional babies each year.^{11,12}

Products for women and children each account for about a quarter of the current complementary medicines market.

Consumer trends

Health, and the health of their children, regularly rank at or near the top of surveys of Chinese consumer concerns. Safety and quality of food and the potential effects of environmental pollution are also key consumer concerns driving increased interest in nutritional supplements and health products.

Another contributor to demand is the global health and wellness trend and interest in the relationship between nutrition and health, which is driving more consumers to take an active role in managing their health.

The limited availability of mainstream medical services is also a factor driving demand for complementary health products. China's healthcare infrastructure and resources are unevenly distributed, meaning many consumers have inadequate or unsatisfactory access to primary healthcare and are looking to health foods to help maintain their wellbeing.¹³

Health reforms and the Healthy China 2020 Strategy

China adopted its 13th Five-Year Plan in March 2016. The Plan includes the Healthy China 2020 strategy, an ambitious plan to transform the country's health and aged care industry. The strategy sets out a number of priorities, including several that support demand for complementary medicines:

- › Adhering to the principle of 'prevention first' to better address China's current disease burden and the growing prevalence of chronic diseases.

- › Ensuring food and drug safety across the country by bolstering safety management efforts in rural areas, and reforming the review and approval system for drugs and medical devices.
- › Promoting the development of traditional Chinese medicine (TCM) by building research institutions and accelerating the standardisation of TCM products and services.¹⁴

China-Australia Free Trade Agreement

The China-Australia Free Trade Agreement (ChAFTA), which entered into force on 20 December 2015, significantly enhances Australia's economic relationship with China by providing Australians with a competitive edge in China across a range of key business interests, including goods, services and investment.

Australia's complementary medicines sector stands to benefit from the elimination of tariffs of up to 10 per cent on pharmaceuticals, including vitamins and health products.

Australia and China have undertaken to strengthen cooperation on TCM including agreeing to encourage and support engagement between relevant professional bodies and registration authorities for TCM practitioners in both countries and to encourage and support research and development into TCM.



Products by category

Health foods

While health foods based on TCM principles have been consumed in China for thousands of years, the modern concept of health foods, in terms of formula, manufacture and packaging, only emerged in the 1980s.

As at 16 June 2016, there were 14,946 Chinese and 664 international health food products registered by the China Food and Drug Administration (CFDA) on the market. These products have a health food number and a logo, known as a Blue Hat. International health foods with a Blue Hat logo make up 4.25 per cent of total health foods registered by the CFDA. International health foods, both with and without a Blue Hat logo, had a 50 per cent share of the market.¹⁵

Health foods in China are categorised either as health foods with functional claims or nutritional supplements.

Health foods with functional claims

Health foods with functional claims comprise about 65 per cent of the Chinese health food market. Functional claims need to be approved by the CFDA to be given a Blue Hat logo. The CFDA has currently approved 27 health food functional claims, as shown in Table 2.

Nutritional supplements

Nutritional supplements, including vitamins and mineral products, account for about 35 per cent of the Chinese health food market. In 2015, Chinese consumers purchased over RMB109 billion (US\$16.3 billion) of vitamins and dietary supplements. This market is predicted to reach RMB149 billion (US\$22.3 billion) by 2020, with a compound annual growth rate of 6.4 per cent from 2015–20.¹⁷

Table 2: CFDA-approved health food functional claims¹⁶

NO.	FUNCTIONAL CLAIM	CHINESE NAME – 功能名称
1	Enhances immune function	增强免疫力功能
2	Assists in lowering blood lipids	辅助降血脂功能
3	Assists in lowering blood sugar	辅助降血糖功能
4	Contains antioxidants	抗氧化功能
5	Assists in improving memory function	辅助改善记忆功能
6	Relieves eye fatigue	缓解视疲劳功能
7	Facilitates lead excretion	促进排铅功能
8	Eases throat disorders	清咽功能
9	Assists in lowering blood pressure	辅助降血压功能
10	Improves sleep	改善睡眠功能
11	Facilitates lactation	促进泌乳功能
12	Alleviates physical fatigue	缓解体力疲劳
13	Assists anoxia tolerance	提高缺氧耐受功能
14	Assists in protection from radiation	对辐射危害有辅助保护功能
15	Facilitates weight loss	减肥功能
16	Improves growth and development	改善生长发育功能
17	Increases bone density	增加骨密度功能
18	Improves nutritional anaemia	改善营养性贫血
19	Assists liver function	对化学肝损伤有辅助保护功能
20	Reduces acne	祛痤疮功能
21	Dispels chloasma	祛黄褐斑功能
22	Improves skin moisture	改善皮肤水份功能
23	Cleanses oily skin	改善皮肤油份功能
24	Improves intestinal flora	调节肠道菌群功能
25	Promotes digestion	促进消化功能
26	Relieves constipation	通便功能
27	Assists in protecting gastric mucosa	对胃粘膜损伤有辅助保护功能

Source: CFDA, [Scope of Health Food Function](#)



35%

MARKET SHARE OF NUTRITIONAL SUPPLEMENTS



US\$22.3bn

VALUE OF NUTRITIONAL SUPPLEMENTS MARKET BY 2020



65%

MARKET SHARE OF HEALTH FOODS WITH FUNCTIONAL CLAIMS

The major Australian exporters of vitamins, minerals and supplements – Swisse and Blackmores – have seen rapid growth in sales over 2015, with online channels driving this growth.

In January 2016, the China Healthcare Association and Shuzheng Health (Beijing) Commercial Consultation Co., Ltd jointly released a list of the top 10 e-commerce health brands in 2015. This included three Chinese brands – By-health (No. 2), CPT (No. 5) and Xiuzheng (No. 7).

Over-the-counter medicines

In 2015, over-the-counter (OTC) medicine sales accounted for 15 per cent of total pharmaceutical sales in China. The Chinese OTC medicine market was valued at RMB174 billion (US\$26 billion) in 2015, an increase of six per cent on the previous year.¹⁹

China's booming economy is a key reason for the growth of the OTC medicine market, driving demand for products that alleviate minor health complaints, such as headaches, indigestion and fever. A sizeable proportion of increased OTC medicine sales comes from first-time buyers.

OTC medicines and vitamins and dietary supplements have the greatest presence in chemists and pharmacies, and this channel commanded a retail value share of 49 per cent in 2015. Chemists and pharmacies are the dominant distribution channel for OTC medicines, accounting for more than 60 per cent of sales in 2015. Chemists, pharmacies and internet retailers are winning sales from other channels such as supermarkets and hypermarkets because they are perceived to offer a more professional service to consumers.

Table 3: Top 10 e-commerce health brands, 2015¹⁸

RANK	OVERALL TOP 10	CHINESE TOP 10	INTERNATIONAL TOP 10
1	Swisse	By-health	Swisse
2	By-health	CPT	Herbalife
3	Herbalife	Xiuzheng	Amway
4	Amway	Simeitol	GNC
5	CPT	Guozhen	Puritan's Pride
6	GNC	Conba	MuscleTech
7	Xiuzheng	Wanmei	Blackmores
8	Puritan's Pride	Difiney	MET-Rx
9	MuscleTech	Infinitus	Nature's Bounty
10	Blackmores	Yangshengtang	Usana

Source: China Healthcare Association, 2015's top ten e-commerce healthcare products – international brands lead the way, 4 January 2016, accessed 7 February 2017.

Food for special medical purpose

Food for special medical purpose (FSMP) refers to foods specifically formulated and processed to meet the special dietary or nutritional needs of patients with dietary restrictions, digestive and/or absorption disorders, metabolic disorders or special diseases with respect to nutrients or diets.²⁰ Regulations for the registration of FSMP came into force on 1 July 2016, marking the official start of this market and attracting attention from food and pharmaceutical companies.

Prior to China's enforcement of regulations governing the registration of FSMP, these foods included drugs, special dietary foods, normal foods and health foods. For example, enteral nutrition preparations used to be registered as drugs, and overseas companies such as Abbott, Nutricia and Nestlé that sell these preparations entered the Chinese FSMP market in this way.

Only 1.6 per cent of patients suffering from malnutrition in China are consuming FSMP, compared with 65 per cent in the US and 27 per cent in the UK.²¹ In some small cities, even doctors lack knowledge about FSMP.

China's current FSMP consumption is valued at RMB600 million, but the market is predicted to grow to RMB10 billion when it matures.

Sports supplements

China's sports supplement market emerged around 1998. At that time, only a small variety of protein, creatine and amino acid powders were available. Prices were high and uptake was limited to a small number of consumers.

However, within a few years the market had expanded dramatically. Many sports supplement companies were created and numerous domestic and international brands began to appear. The market became especially competitive from 2004 to 2010.

While there are now fewer sports supplement companies than in 2004, the surviving businesses have generally grown strongly. One company, Beijing Competitor Sports Science & Technology Co., Ltd, has achieved a year-on-year growth rate of more than 50 per cent over 10 consecutive years and has become the leading domestic sports supplement manufacturer in China, with total assets of RMB683 million.²²

Euromonitor International reported that sports nutrition in China recorded double-digit value growth in 2016.²³ The sports supplement market has been attracting leading Chinese health food companies. For example, By-health, which has overall sales revenue of RMB1.2 billion, recently entered this category with the launch of a dedicated sports supplement brand, GymMax.

Recognising a gap between China's sports industry and that of developed countries, the PRC State Council has announced a goal to grow the overall sports industry to RMB5 trillion by 2025. The government plans to encourage food and pharmaceutical manufacturers to develop sports-related products.²⁴

Market trends

The complementary medicines market is experiencing ongoing regulatory and commercial changes that exporters will have to take into account when entering China.

An increasingly regulated market

Customers in China have high expectations about the protection of their consumer rights. A recent survey on health food consumer awareness found 76 per cent of consumers expect the government to supervise the industry and enforce laws about false advertising, and 57 per cent expect the government to set rigid laws and standards.²⁵

As a result of various government policies and initiatives, the health food market in China is becoming increasingly regulated and moving towards a system that provides consumers with the assurance they seek.

The introduction of the Blue Hat logo, combined with the recent streamlining of the registration and filing process, makes it easier to identify health foods with functional claims. Health claims have become more standardised and credible, with regulations prohibiting health foods from claiming they can cure illnesses.

Stringent advertising regulations mean it is much more risky for companies to make unapproved or exaggerated claims about health food products. China's advertising laws strictly prohibit false or misleading information, or presenting information in an inappropriately competitive way. The days of making rapid and lucrative sales through unrealistic promises are gone, as government regulators, consumers and professional claimants are quick to pursue offenders.

Further information on advertising and professional claimants is provided in this guide under 'Common Risks and How to Avoid Them.'

The Chinese Government is expected to continue reviewing its systems for regulating registration, distribution and advertising of health food products, to ensure a fair competitive environment.

Streamlining the registration process

In response to pressure to improve and streamline the health food registration process, a new CFDA regulation that pre-qualifies certain ingredients came into effect on 1 July 2016. If ingredients of a health food product have been pre-qualified, then recorded filing, instead of a complicated registration approval procedure, is sufficient for approval of that product.

Increased potential for products based on TCM principles

Consumption of TCM in China is huge, as it is a long-established and trusted form of medicine. A 2016 Chinese Government white paper reported that China has approximately 4,000 TCM hospitals and over 42,000 TCM clinics. Additionally, most large public hospitals have TCM departments. In 2015, there were 910 million visits to TCM practices nationwide.²⁶

There are clear opportunities for products based on TCM principles to be developed for, and promoted to, Chinese consumers. Foreign brands with established reputations for quality and attention to detail are particularly well placed to benefit from strong Chinese consumer interest in, and demand for, TCM-based products.

To capture a share of the TCM opportunity in China, Australian companies need to build their product portfolios of TCM components. In May 2016, Blackmores announced the acquisition of Global Therapeutics, Australia's leading provider of retail Chinese herbal medicine formulations through the trademarked brands Fusion and Oriental Botanicals.²⁷

Raw ingredients are another potential opportunity. More than 6,500 Chinese medicinal herbs have been identified, and Customs figures indicate China exports 240,000 tonnes of medicines annually, of which 200,000 tonnes are raw herbs. These raw herb exports accounted for 20 per cent of the country's annual harvest.²⁸

However, due to continuing environmental contamination in the soil and overuse of chemicals, herbs are often found to have excessive levels of heavy metal and chemicals. This not only affects the exportability of raw herbs, but also their medicinal properties. As a result, high-value Chinese herbs and other raw materials planted or obtained from Australia are now on the agenda for many big pharmaceutical companies and potential investors from China. Although there are still no specific protocols in place, it seems likely Chinese companies will be interested in sourcing 'clean, green and safe' raw materials from Australia in the future.

In TCM practice, the exact location where a particular herb is planted (in Chinese: **道地药材** *dao di yao cai*) is crucial to its effectiveness, and thorough preliminary evaluations of factors like weather, temperature, humidity and soil type at a site are necessary. One Chinese pharmaceutical company is currently exploring the possibility of planting ginseng in Tasmania for export back to China.

Continuing importance of online channels

China is the largest online retail market in the world. E-commerce has proven to be a very important channel for Chinese and international health food brands. Although the Chinese Government has tightened regulations on cross-border e-commerce, the channel remains an effective way for many foreign products to enter the Chinese market, with comparatively easy market access and a favourable tariff policy.

In 2015, online retail sales totalled RMB3.88 trillion, a growth of 33.3 per cent from 2014. Online retail sales of foods increased by 41 per cent.²⁹

Austrade's [E-commerce in China: A guide for Australian business](#) provides information about the rapid growth of e-commerce in China and the resulting opportunities for Australian businesses.

In addition to being a retail channel, the internet is one of the main ways Chinese consumers research health products. A survey by the China Consumers' Association found 63 per cent of consumers obtained information about health foods from online sources, with 70 per cent getting information from TV commercials.³⁰

More diversified products

As they become more sophisticated in health food consumption and receive more tailored healthcare advice, consumers are demanding a more diversified range of products. Many leading health food companies have responded to this trend, such as By-health, which launched three new sports supplements, and women's health and high-value TCM products in 2015.

REGULATORY REQUIREMENTS

China and Australia have differing definitions around complementary medicines and health foods, which carry a range of regulatory implications.

Complementary medicines are not a legal concept under Chinese law. Although not legally defined, such products fall under various categories that are regulated. Most would be categorised as food, but products containing ingredients defined in China as a medical ingredient may fall under the category of medicines, or cosmetics if used externally and not for medicinal purposes (e.g. some aromatherapy oils). This guide focuses on food as it is the most widespread category for complementary medicines.

The [China Food and Drug Administration \(CFDA\)](#) is the national authority for all health food, OTC medicines and food safety matters. Exporters should refer to the CFDA's Chinese website as most of the latest information on rules and regulations will be issued in Chinese.

Definitions

In Australia, complementary medicines and natural healthcare products include vitamins, mineral and nutritional supplements, special purpose foods, herbal and homoeopathic medicines and certain aromatherapy products. A complementary medicine is defined as a therapeutic good consisting principally of one or more designated active ingredients, each of which has a clearly established identity and traditional use.

Complementary medicines are subject to Australia's risk-based approach, with its two-tiered system for regulating all medicines. Lower-risk products can be listed on the Australian Register of Therapeutic Goods (ARTG) and are allocated an 'AUST L' number. Higher-risk products must be registered on the ARTG and are allocated an 'AUST R' number.³¹

In China, 'food' can be divided into normal food and special foods. Normal food is comparatively lightly regulated, whereas special foods are subject to special registration or filing requirements. These depend on whether the product is categorised as health food, infant formula or food for special medical purpose (FSMP). At present, complementary medicines mostly fall under the categories of normal food, health food and FSMP.

Food categories in China

In Chinese law, food refers to processed and unprocessed substances consumed by human beings and substances that are traditionally regarded as both food and Chinese medicinal materials, but excluding substances for treating illness.³²

Normal food

There is no explicit definition for normal food under Chinese law. Generally speaking, normal food refers to standard, long-duration and/or preserved food products that are suitable for human consumption and do not fall into the category of special food.

Special food

Special food, as categorised by China's Food Safety Law, includes health food, infant formula and FSMP. Health food and FSMP are most relevant to complementary medicines.³³

Health food

Health food (保健食品, bao jian shi pin) is food that claims to have health functions or can supplement vitamins and minerals in the human body. It is food that targets certain groups of people and helps adjust their bodily functions. Health food can claim to promote wellness but cannot make any claim to heal illness or have a specific effect on human health. Health food is prohibited from producing any acute, sub-acute or chronic hazard to human health – although this would presumably be equally applicable to normal food.³⁴

Health food can be further divided into two categories:

- > **Nutritional supplements** such as vitamins and minerals, which are required to obtain a CFDA filing.
- > **Functional health foods**, which are products claiming a specific health function as permitted by the function list issued by the CFDA. Functional health foods are required to obtain CFDA registration (i.e. the Blue Hat logo).

Food for special medical purpose (FSMP)

According to the Administrative Measures for the Registration of Food for Special Medical Purposes, FSMP is food specially formulated to meet the nutritional and/or dietary needs of individuals who contract a specific disease, disorder or medical condition and who have limited or impaired capacity to take, digest, absorb or metabolise ordinary food. The Measures divide FSMP into two age categories: infants under 12 months of age, and people over 12 months of age.³⁵

FSMP must be used under the guidance of a doctor or clinical nutritionist. FSMP is considered to be food, not drugs, and cannot be used as a substitute for a drug. FSMP cannot make any claims regarding disease prevention or therapeutic function.

Regulations for food categories

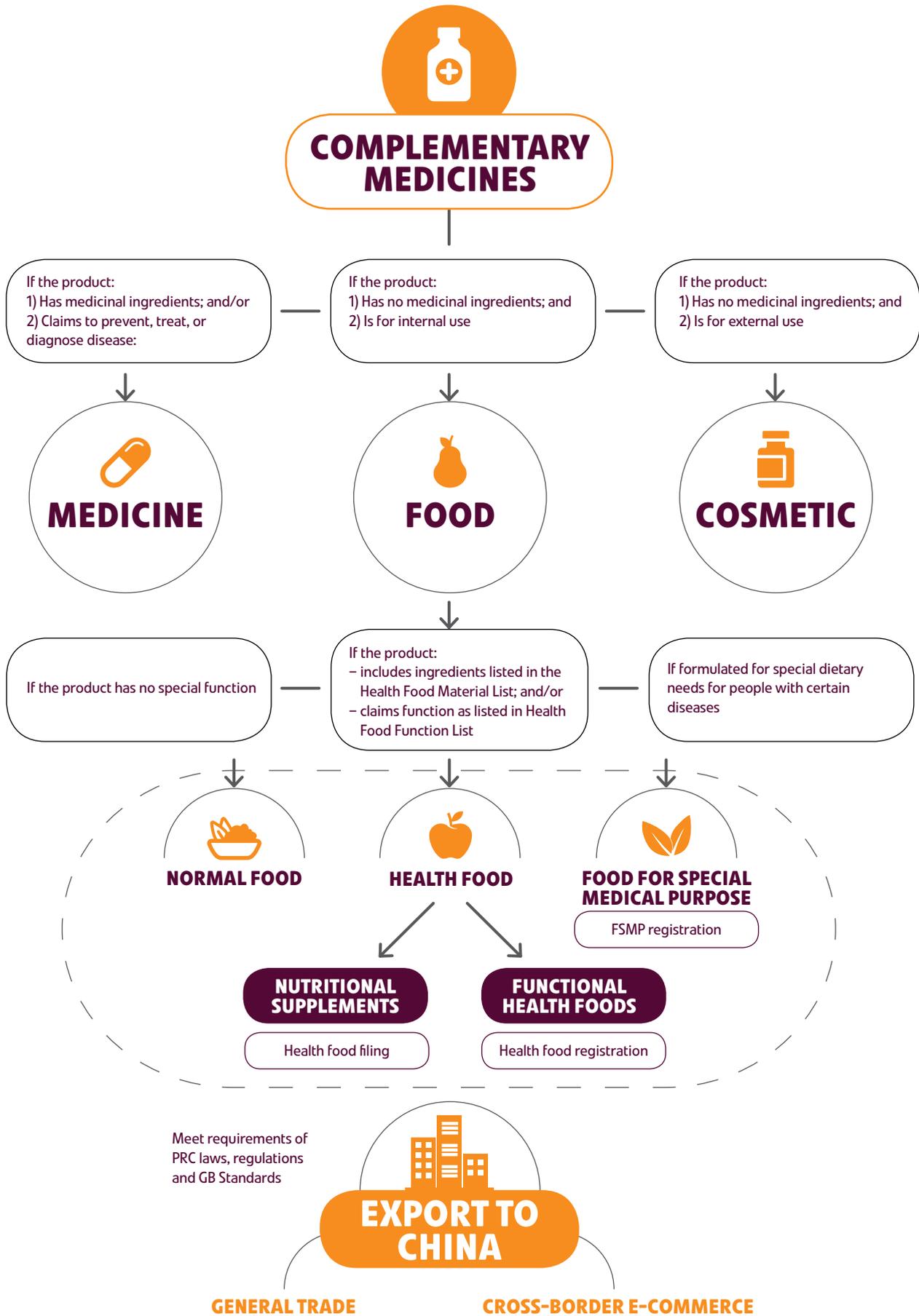
Under China's Food Safety Law, different regulatory requirements apply to each category of food. These determine:

- › which specific product regulations apply, including regulation on registration or filing, labelling and advertising
- › the specific registration or filing that must be obtained for each product e.g. normal food does not require special registration or filing, whereas health food requires registration or filing, depending on whether the product is a nutritional supplement requiring FSMP registration
- › which functional claims can be made regarding the food e.g. normal food cannot claim it promotes good health ('an apple a day keeps the doctor away' would not be permitted in China), whereas health foods cannot claim to cure or prevent disease and illness
- › whether the product can be distributed through the cross-border e-commerce model.

Figure 4 illustrates how complementary medicines can fall under each food category and the resulting regulatory implications.



Figure 4: Complementary medicines categories and regulation implication



Product registration and filing

Normal food

The easiest and most common route for international companies is to import complementary medicines into China as normal food. Normal food is not subject to any special registration or filing requirements. Food will need to comply with general Chinese laws and regulations, national food safety standards and any other national standards that apply to the specific product ('GB standards').

More detailed examination and reviewing rules may apply to some categories of food.

Health food

Health food is the most strictly regulated of the food categories. A new Food Safety Law came into force in 2015, changing the single-track registration system to a dual-track registration and filing system.

Under the old single-track system, all health food products were required to obtain CFDA registration. However, there was room to blur the boundaries between health food and normal food, which led many international companies to declare nutritional supplements, as well as animal oil products, to be normal food to avoid registration requirements. Although this did not comply with the relevant regulations from a legal perspective, a lack of specific penalties allowed such practices to become widespread.

The new dual-track registration and filing system was intended to address the problem of companies failing to register products properly under the old system. Under the new system, only functional health foods require registration, whereas nutritional supplements (which are considered lower-risk and are commonly used) only require filing. In addition, the 2015 Food Safety Law also created a pathway towards a more comprehensive system by designating a function list as well as materials and ingredients lists. These lists will help clarify whether or not a product should be categorised as health food, what ingredients can be used in health food and what functions a product can claim.

At present, only two lists relating to health food registration and filing have been issued since the dual-track system came into effect:

- › [List of Health Food Raw Materials \(First Batch\) – List of Nutritional Supplements Raw Material](#)
- › [List of Permitted Health Claims for Health Food \(First Batch\) – Function List of Nutritional Supplements.](#)

The following lists about health food filing have been issued in draft form for public comment. Once officially adopted, they will determine which raw materials and auxiliary materials can be used in nutritional supplements:

- › [List of Permitted Auxiliary Materials for Health Food Filing \(First Batch\) \(Draft\)](#)
- › [List of Permitted Auxiliary Materials for Health Food Filing which Require Further Verification \(Draft\).](#)

The following lists issued under the old system may be replaced by new ones progressively but remain in force until further notice:

- › [Notice on Adjusting the Acceptance and Approval Scope of Health Food Function](#) – issued by the Ministry of Health on 14 January 2000. This notice provided a list of functions which can be claimed by functional health foods.
- › [Notice on Further Regulating the Administration of Health Food Materials](#) – issued by the Ministry of Health on 28 February 2002.

This notice sets out:

- › a list of substances for both medicine and food
- › a list of substances which can be used in health food
- › a list of substances prohibited from use in health food.

These three lists determine which substances can be used, and which are prohibited from use, in health food.

Health food registration or filing

Under the dual-track registration and filing system, nutritional supplements such as vitamins and minerals need only to proceed with a filing. All other health food products to be imported into China for the first time must be registered.

In February 2016, the CFDA published the Administrative Measures on Health Food Registration and Filing (the '2016 Measures'), which provides detailed implementation rules for registration and filing.

In December 2016, the CFDA released its [Guidance for Review and Approval of Health Food Registration Applications](#), which provides more detailed requirements on document submission and review and approval procedures for health food registration. The Guidance applies to registration applications for health food using ingredients which are outside the above list of health food raw materials, and health food imported for the first time (excluding vitamins and mineral supplements). The Guidance also covers the application requirements for extending registrations, changing registrations, technical transfer, certificate reissue, products using extracts as the raw materials and imported products.

Registration is a significantly more complex procedure than filing. Table 4 describes the registration and filing criteria for different product types.

Table 4: Registration and filing criteria

ITEM	REGISTRATION REQUIRED	FILING REQUIRED
Applicable scope	<p>(a) Products using ingredients other than those included in the list of health food raw materials.</p> <p>(b) Products imported into China for the first time, including products previously imported into China but have had a change of formula or manufacturer (excluding products which are purely nutritional supplements).</p>	<p>(a) Products using ingredients that are included in the list of health food raw materials.</p> <p>(b) Nutritional supplements imported into China for the first time.</p>
Applicant for health food to be imported	Overseas product manufacturers. Note: The application should be submitted by the applicant's representative office in China or by a domestic agent engaged by the applicant.	

Table 5: Key documents required for filing or registration

APPLICATION DOCUMENTS	REGISTRATION FOR PRC HEALTH FOOD	REGISTRATION FOR FIRST-TIME IMPORTED HEALTH FOOD	FILING FOR IMPORTED HEALTH FOOD
I. Research report, including data for scientific basis of product, function and technical specifications	√	√	X
II. Formula description, including basis of ingredients used	√	√	√
III. Description of manufacturing process, including flowchart and instructions	√	√	√
IV. Evaluation of unlisted ingredients, including evaluation of safety and healthcare functions of any ingredients not listed in the Health Food Ingredient Catalogue	√	√	√
V. Packaging, including details of type, name and relevant standards of the immediate packaging materials	√	√	√
VI. Labelling, including providing a sample of labels and instructions, and retrieval documents proving the generic name of the health food product is different from registered drug names	√	√	√
VII. Qualification certificate issued by the competent authority in the country of origin to prove the applicant is a qualified overseas manufacturer of the product	X	√	√
VIII. Evidence the health food has been sold in a relevant market for at least one year or, failing this, a safety report issued by the competent authority in the country of origin	X	√	√
IX. Relevant technical regulations or standards for health foods in the country of origin	X	√	√
X. Sample of packaging, label and instructions for product as sold in country of origin	X	√	√
XI. The product's technical specifications	X	X	√
XII. Test reports issued by a qualified testing institution as evidence the product complies with all technical requirements	X	X	√
XIII. Supporting documents to prove product safety and healthcare functions	X	X	√
XIV. Other documents as required	√	√	√

Materials to be submitted for registration or filing

A number of documents must be submitted for registration or filing of health food in China. Key documents to be submitted for each type of registration or filing are shown in Table 5.

Registration versus filing

As outlined above, the documentation needed for a filing or a registration is not substantially different. However, the key difference between registration and filing is the level of scrutiny applied by the CFDA. A registration is issued after review and approval. In comparison, a filing is issued after all relevant documents have been submitted.

Registration is more time-consuming and complex. In some cases, a Blue Hat registration may take two to three years and can be very costly. If a company wants to make a functional effect claim for its product, then this may necessitate human testing, which can take up to 36 months longer.

Although the filing procedure will be simpler for most companies, the following two eligibility requirements may be problematic for some supplement companies:

- › The ingredients in the product must be included in the list of health food raw materials (see above); and
- › The company must provide evidence the product has been sold for at least one year in its country of manufacture ('one-year sale proof').

The potential challenge is that a number of materials commonly used in other countries, such as soy protein and some fruit juice powders, are not officially recognised by the CFDA. If any of the materials or ingredients used in a nutritional supplement are not included in the relevant CFDA lists, then the affected products will need to undergo registration rather than filing. In such cases, the international company is also unable to adjust its overseas product to meet Chinese standards, as the one-year sale proof test requires the imported product to be exactly the same as the version sold in the country of manufacture in terms of ingredients, dosage and levels.

Penalties

The new system provides specific penalties for failing to obtain the relevant registration or filing for a product. This change greatly increases the risk for companies that import health food as normal food to avoid registration. Companies that manufacture or sell health food that has not obtained registration as required will:

- › have their illegal income, illegal product, and the equipment and materials used for such illegal production confiscated
- › be fined between RMB50,000 and RMB100,000 if the value of the illegal product is less than RMB10,000, or be fined between 10 to 20 times the value of the illegal product if the value of the product exceeds RMB10,000
- › have their business licence revoked in serious cases.

If the manufacturer fails to obtain the filing as required, the CFDA may:

- › order the manufacturer to rectify the situation
- › impose a fine between RMB5,000 and RMB50,000 if the manufacturer fails to rectify the situation
- › order the manufacturer to cease business and revoke its business licence in serious cases.

Food for special medical purpose

FSMP that will be manufactured, sold within or imported into China must be registered with the CFDA.

Both domestic and overseas manufacturers can apply to the CFDA for FSMP registration only if they have:

- › sufficient R&D and manufacturing capacity to produce FSMP
- › R&D, food safety management and technical personnel
- › production management systems
- › capability to inspect all items on a batch-by-batch basis.

Materials to be submitted for registration

A FSMP registration application requires:

- › an R&D report of the product, formula and its scientific basis
- › production process data
- › product standards
- › samples of labels and instructions
- › inspection report of laboratory samples
- › supporting documents to prove R&D capability, production and inspection
- › a clinical trials report, if applying to register food with specific full-nutritional formula (this is FSMP that is consumed as the single nutrient source to meet the nutritional needs of target groups)
- › documentation providing evidence of the FSMP's safety, nutritional value and clinical efficacy.

Regulation trends

Although China's increasing regulation of imported food and health food has attracted significant international attention, the recent updates to regulations have helped rationalise and streamline health food importation processes and simplified the regulatory regime.

The 2016 Administrative Measures provided greater clarity around the approvals required for complementary medicines and health foods to enter the Chinese market.

Under the new practice, domestically manufactured products – the ingredients of which are included in the health food ingredient lists – and nutritional supplements imported into China for the first time can be approved for production or importation through the filing process, rather than undergoing the lengthy registration process.

In practical terms, this will mean a large number of health food products will be exempt from registration requirements based on the new ingredients-based regime, compared to the previous products-based regulatory regime. In addition, the registration process is likely to be simplified, as companies can submit applications directly to the central CFDA, eliminating the need for preliminary testing with the provincial-level CFDA.

EXPORTING TO CHINA

Having the right product and getting it registered or filed with the Chinese authorities is only the beginning of the export process. The next steps are finding the right distribution channel, building a brand and knowing how to avoid common pitfalls.

Most international companies intending to sell complementary medicines in China adopt one or a combination of the following models:

- › General trade – through Chinese importers and/or distributors
- › Cross-border e-commerce (including direct shipping and bonded zone models)
- › Postal route
- › Manufacturing in China.

There are also cases of Chinese or Hong Kong companies investing in complementary medicine businesses or buying them outright so the acquired businesses can gain better access to the China market.

General trade

The traditional approach to importing food and health food into China was via the general trade model. This means products are imported into China through regular Customs, Inspection and Quarantine (CIQ) channels.

The arrangement, which usually involves an offshore exporter and a Chinese importer or distributor, continues to be the main distribution channel for imported food and complementary medicines.

Engaging a distributor or establishing a wholly foreign-owned entity (WFOE) to import and distribute the products means the participating parties will be subject to Chinese importation laws. The imported products are required to comply with Chinese laws and regulations as well as GB standards. For complementary medicines, the filing and registration requirements described in the Regulatory Requirements section will also apply, if the complementary medicines and functional health foods fall under the corresponding food category according to Chinese law.

Registration and filing requirements

In addition to product filing or registration, the manufacturer, importer and distributor are subject to additional requirements under the general trade model, which vary depending on the type of product. These requirements are detailed below.

Import procedures

In addition to filing and/or registration, importers need to follow certain procedures as set out in table 6.

Inspection and quarantine

For each batch of imported products, the following materials must be submitted to the CIQ authority to determine if the products meet Chinese requirements and GB standards:

- › contract, invoice and bill of lading
- › sanitary certificate issued by exporter's government authority
- › certificates of origin
- › testing reports
- › registration/filing certificate for each type of special food as described in the Regulatory Requirements section
- › sample of label and translation (only required for products being imported for the first time).

As it can take months or even years to obtain the registration/filing certificate for special foods, the offshore manufacturer and exporter must plan ahead and ensure everything is in place before exporting to China.

Labelling requirements

All products imported into China must have a Chinese language label that complies with Chinese laws and regulations and GB standards. Legal requirements around labelling are very detailed and functional claims are closely monitored, so developing the Chinese label can be a major issue for international manufacturers.

Specific labelling requirements apply to health foods and FSMP. They:

- › cannot claim to treat or prevent disease or illness
- › must expressly state they cannot substitute for medicine
- › must only have function claims described in the CFDA-approved Function List (see Table 2).

FSMP must observe Chinese advertising laws, as well as regulations around the promotion and advertisement of medicines.

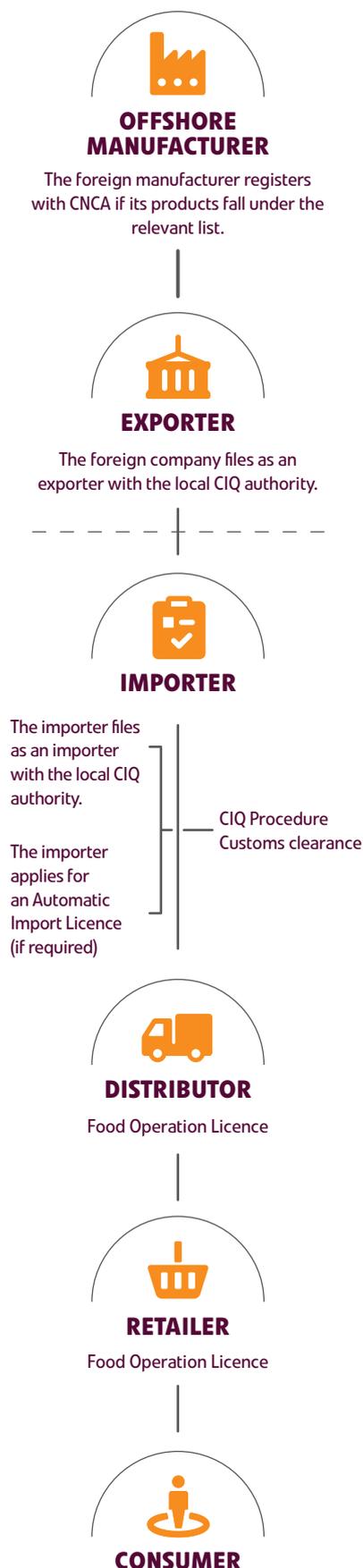
Customs clearance

After passing inspection and quarantine procedures, products can be declared to Customs. To do this, companies must submit documentation that enables Customs to determine the customs duty based on the product's HS code.

Table 6: Filing or registration requirements for general trade

TASK/LICENCE/CERTIFICATE	TYPICAL TIMEFRAME	COMMENTS
1 Offshore manufactured products – CNCA registration in special cases	Up to 6 months	Some products imported into China require the overseas manufacturer to pass CNCA registration. A list of affected products is issued annually. For 2016, the affected products are meat, dairy products, seafood and edible bird nests. Relatively few complementary medicines are likely to be affected in the future – typically only those containing dairy products. If a product falls into this category, the foreign manufacturer will need an official recommendation from its home country authorities to submit to the CNCA. The CNCA will review the products and may conduct an overseas onsite review. The CNCA registration can take at least six months.
2 Offshore exporter filing as food exporter	At least 1 week	A company exporting food products to China must file with the CIQ authority. This is a straightforward filing and only requires basic information from the exporter.
3 Onshore importer filing as food importer	At least 1 week	The importer needs to file with the CIQ authority. The requirements for the filing include having: <ul style="list-style-type: none"> > a quality and safety management system > a relevant food safety organisational setup > storage for the food products being imported.
4 Onshore importer – automatic MOFCOM import licence	At least 2 weeks	Some food products require the importer to obtain an automatic import licence. The affected products are primarily commodities such as meat, grain and dairy products. This licence is unlikely to be required for complementary medicines or functional health foods unless they contain these products. If required, the application must be made at the local Ministry of Commerce (MOFCOM) authority before customs clearance of each batch of imported products.
5 Onshore distributor and retailer – CFDA Food Operation Licence	4–6 weeks	Any company selling food in China under its own name must obtain a Food Operation Licence from the CFDA. The main requirements for obtaining a Food Operation Licence include having: <ul style="list-style-type: none"> > premises, equipment and facilities appropriate for the type and quantity of food to be distributed > food safety technicians, management personnel and rules and regulations to ensure food safety > appropriate equipment layout and technical processes to avoid cross-contamination between foods and toxic or unclean substances.

Figure 5: General trade model





Cross-border e-commerce

Austrade's [E-commerce in China: A guide for Australian business](#), provides advice for Australian businesses considering e-commerce in China. Please refer to that guide for additional information on using e-commerce channels in China.

After a year-long review of the tax and regulatory framework for cross-border e-commerce, the Chinese Government announced in March 2017 that the existing framework will remain relatively intact. Austrade advises all exporters considering e-commerce channels to seek independent professional advice.

Overview

Although general trade is the traditional and most common way of exporting to China, there has been a dramatic increase in cross-border e-commerce in the last few years, driven largely by the rise of China's consumer class and the Chinese Government's promotion of trade through bonded zones.

The two most common cross-border e-commerce models are:

- › **direct shipping:** a foreign company sells products to Chinese consumers via a website and products are directly delivered to them from abroad.
- › **bonded zone:** products are delivered and stored in an onshore bonded zone in batches. Products are then sold to consumers via a website, and delivered to them from the bonded zone.

Prior to April 2016, cross-border e-commerce was lightly regulated, with little in the way of national-level regulations and few regulations around practical implementation issues. At that time, supervision was mostly based on rules issued by individual local authorities or unpublished 'practical rules' adopted by local authorities for their own purposes.

This environment was seen as a great opportunity by many international companies interested in selling to the rapidly growing Chinese consumer class, particularly vitamin and supplement manufacturers. Cross-border e-commerce presents advantages in:

- › shipping products to China that do not have to comply with strict Chinese laws, regulations or GB standards and are exempt from the filing and registration requirements for special foods

- › passing on lower costs to Chinese consumers, as sales are considered to be personal imports and therefore subject to the postal tax rate
- › avoiding the requirement to have Chinese labels
- › gaining access to easy and expedited CIQ clearance.

However, this lack of regulation and largely tax-free treatment was not going to be sustainable in the long term. As expected, Chinese authorities have started to exercise increasing oversight over the multibillion-dollar industry.

Recent changes

On 24 March 2016, Chinese authorities issued the Circular on Tax Policy for E-Commerce Retail Imports ('E-Commerce Circular'), followed by two Cross-border E-commerce Retail Lists of Imported Goods in April 2016 ('Positive Lists'). These new rules created a new regulatory and supervision regime for cross-border e-commerce.

The four main pillars of the new system are described below.

1. Products must be on the Positive Lists to qualify as cross-border e-commerce.

The 'Positive Lists' set out over 1,200 tariff lines for goods that can be imported through cross-border e-commerce. The main types of complementary medicines affected include animal oil, vitamins, minerals and medical products, all of which are listed on the Positive Lists. Any product not listed on the Positive Lists cannot be imported via cross-border e-commerce, regardless of whether or not it has Chinese registration.



2. Health food and FSMP must have appropriate registration or filing.

One of the major advantages for complementary medicines under the old cross-border e-commerce regime was bypassing Chinese registration or filing obligations. This was based on the notion that buying a foreign product online was similar to bringing a product back from overseas in personal luggage.

Under the new regime, products not on the Positive Lists must comply with filing and registration requirements set out under Chinese law.

A transition period is in place and registration and filing requirements will come into force on 1 January 2018.

3. The e-commerce platform must be connected to Chinese Customs.

The new regime states products can only be sold via verified e-commerce platforms that are connected to Chinese Customs, or consistently provide detailed electronic information (i.e. transaction, payment and logistics details). This enables collection of payment and logistics information. If the platform used for cross-border e-commerce sales is not connected to the Chinese Customs system, the seller must provide detailed electronic information to be eligible for the reduced tax rate and expedited Customs clearance available under cross-border e-commerce regulations.

4. Products sold via cross-border e-commerce channels are subject to a new tax system.

Under the new rules, products sold via cross-border e-commerce channels will be subject to a comprehensive tax rate that includes customs duty, value-added tax (VAT) and consumption tax. This is set at a (temporarily) reduced rate.

Currently, the tax rates are:

- › customs duty: 0 per cent
- › VAT at a discounted rate: effectively 11.9 per cent (i.e. 17 per cent x 70 per cent value of goods)
- › consumption tax with a discounted rate: 70 per cent discount (consumption tax normally will not apply to food products, except for tobacco and alcohol).

In addition, the E-Commerce Circular imposed a RMB20,000 annual import quota for purchases by any individual and a limit of RMB2,000 per purchase. Products exceeding these value limits will be subject to the same taxes as general trade.

Although the new regulations will tighten the cross-border e-commerce environment, it appears likely it will retain several advantages compared to general trade:

- › **Shorter supply chain** – compared to the general trade model, cross-border e-commerce involves fewer parties in the sales chain. Chinese consumers tend to be wary of distributors and any layers between them and product suppliers.

A more direct path to consumers helps reinforce trust and confidence, which is particularly important for complementary medicines.

- › **Convenient and expedited CIQ clearance procedures** – being connected to the Customs system enables orders, payments and logistics information to be transferred automatically to the Customs system. It also provides some protection against tax avoidance, formerly a feature of cross-border e-commerce.
- › **Favourable tax treatment** – tax rates for cross-border e-commerce are lower than for general trade.
- › **Less strict labelling requirements** – currently, products sold via cross-border e-commerce channels are not required to have a Chinese label attached and only require the Chinese label information to be displayed on a webpage.

Table 7: Registration process for cross-border e-commerce

TASK/LICENCE/CERTIFICATE	TYPICAL TIMEFRAME	COMMENTS
EXPORTER/DOMESTIC AGENT REGISTRATION		
1 Offshore seller, domestic agent registering as cross-border e-commerce enterprise with local counterparts of CIQ authority	Around 1–2 weeks	Most bonded zone authorities require a domestic agent to be registered within the bonded zone. The offshore seller’s registration is usually made by the domestic agent on the seller’s behalf. The registration requires only basic information about the seller, platform and category of products being sold. Requirements may differ slightly between different bonded zones and should be checked in advance.
2 Domestic seller – Food Operation Licence		If a domestic seller is involved, it will need to obtain a Food Operation Licence as described in the previous section.
PRODUCT REGISTRATION		
3 Product registration with CIQ authority	Around 1 week	This is normally conducted by the domestic agent. Registration mainly requires providing the following information: product name, brand, HS code, specifications, country of origin and name of supplier. Different bonded zones may have different additional requirements; for example, in some bonded zones, the authority will require test reports issued by a qualified testing entity to confirm sanitary requirements have been met. This registration replaces the CIQ authority procedure under general trade, and is generally less strict. The following should also be kept in mind: <ul style="list-style-type: none"> › Products must be on the Positive Lists. › As the national-level CIQ regulations for cross-border e-commerce only provide high-level policies and principles, local CIQ authorities have broad discretion in implementing the regulations and local CIQ practices may vary accordingly.
4 Customs clearance	Dependent on local Customs authority. Within 24 hours in some places	In cases where order information, payment information and logistics information is automatically provided to Customs as part of the process, the products will be cleared automatically, provided the information is consistent.

Selling online: third-party e-commerce platform or own website?

To date, most international companies have teamed up with third-party platforms to sell their products in China. However, some brands are also seeking to drive sales to self-operated websites – often via a Chinese webpage with limited stock-keeping units (SKUs) of the most popular products in China. This webpage contains a link to the brand’s offshore site, which offers an extended range of SKUs that may be sold via the postal route or direct sales model.

Refer to Austrade’s [E-commerce in China: A guide for Australian business](#) for more detailed information on the advantages and disadvantages of different online strategies.

Third-party platform

For the majority of complementary medicines companies, the most likely starting point is a third-party platform, such as Tmall Global or JD.com.

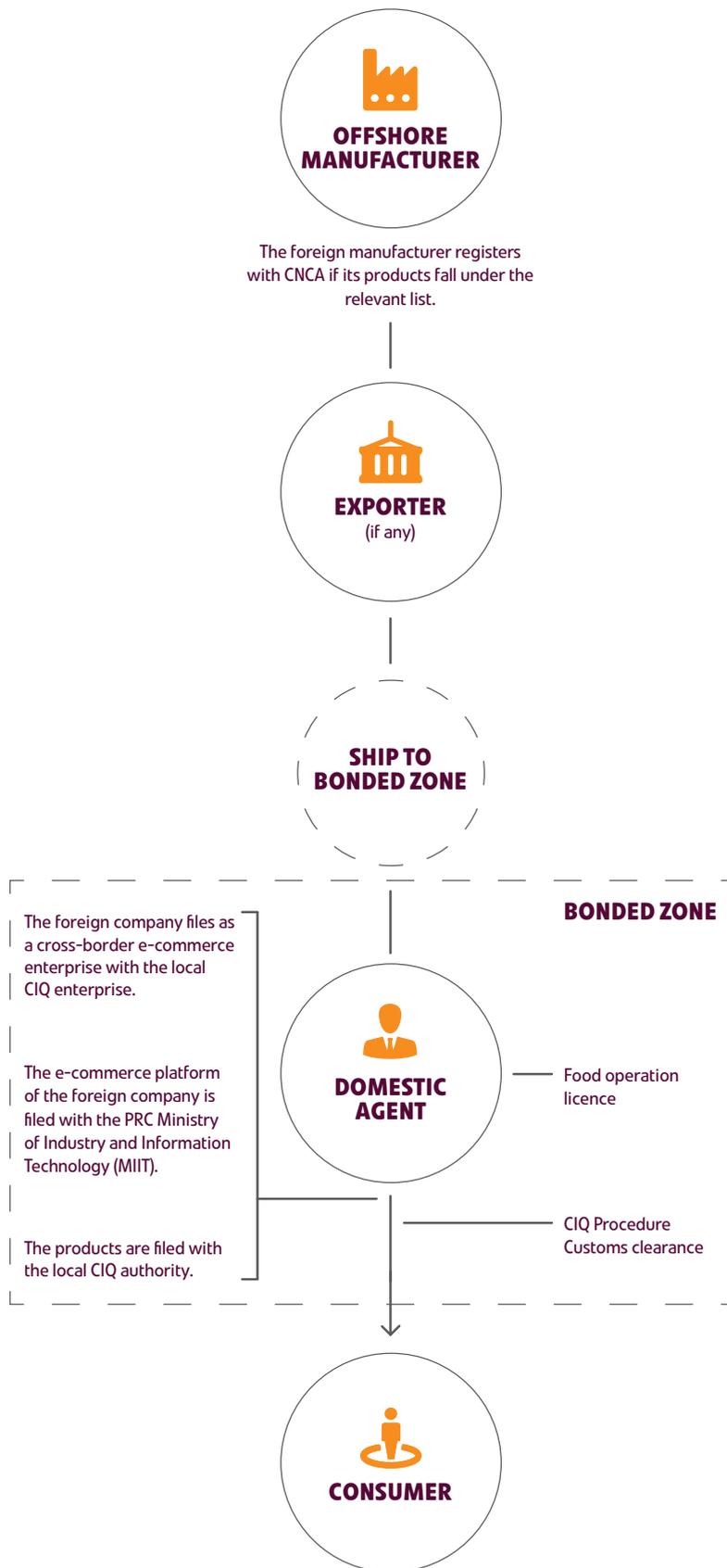
However, it is important to consider individual platform requirements. Tmall Global, for example, requires the company creating the store to be an international entity, and the goods to be produced or sold overseas.

The third-party platform model has the advantages of simplicity and relatively few approval requirements. However, disadvantages include:

- › limited support
- › a risk of being pulled into discount pricing to drive sales
- › a lack of assurance around data confidentiality
- › a lack of scope for companies to build their own platform or connect with consumers in China, as the sites do not allow linking to company webpages.

Figure 6 illustrates the route to market under the cross-border e-commerce model.

Figure 6: Cross-border e-commerce model



Own platform

Establishing a platform to sell products online in China is not necessarily difficult, but needs careful consideration as to whether this is the best strategy.

As long as a company's platform is only selling its own products, then all that is needed is to establish a trading company – which can be wholly owned by foreign investors and up and running within two months – and a filing for internet services ('ICP Filing').

Much stricter requirements apply if the platform allows third parties to sell their products. Establishing a third-party platform would require an internet service registration ('ICP licence'), which, although theoretically possible for foreign companies, is extremely rare because Chinese authorities are reluctant to issue such a licence to wholly foreign-owned enterprises.

Postal route

A postal purchase is considered a personal import and therefore less strictly regulated. Although postal sales were never intended to supplant general trade as a way to ship commercial quantities of goods to China, some complementary medicines companies use this route to sell to Chinese consumers. A common model is consumer-to-consumer (C2C) sellers who buy outside mainland China and then on-sell to Chinese consumers via online platforms such as Taobao. This is known as the 'daigou' model.

The postal route is not intended to be used for shipping commercial quantities of products and is therefore susceptible to government crackdowns. As this route is not part of the official e-commerce channel, it is also not eligible for that model's expedited inspection, quarantine and customs clearance processes. In addition, the postal route is less convenient for Chinese customers; the buyer is responsible for tax on the product and must make a tax declaration, and there are limits on the value of items that can be imported via this route.

C2C sales

The new e-commerce rules introduced in 2016 have not yet had a major impact on sales from websites that are not connected with Chinese Customs or C2C sales. To date, these sales continue to be treated as personal imports. However, as discussed above, the C2C model has limitations and companies wishing to build substantial business in China are unlikely to rely on them in the long term.

Bonded zone model and direct shipping model

The bonded zone model is the most widely adopted cross-border e-commerce model and enjoys government support. The direct shipping model is not widely adopted in the cross-border e-commerce industry, mainly because sending commercial quantities of individual packages from abroad is not cost-effective. Furthermore, not all bonded zones support such a model.

Complementary medicines companies will likely need to adopt the bonded zone model if they wish to build a long-term, e-commerce-based model for exporting to China. As their business grows, international companies may consider general trade and, if business is very successful, manufacturing in China, either by establishing their own facility or through contract manufacture.

Manufacturing in China

International companies that rely on sales of mass products may find general trade or even local manufacturing presents a number of advantages over relying on cross-border imports. This may even be so despite many international companies believing that much of their product's appeal is its overseas manufacture. It is likely that some products will always be imported, but equally likely that at some stage companies will need to manufacture mass products locally or become too vulnerable to changes in Chinese law and regulations. It should be noted that products will still need to comply with Chinese registration requirements.

One advantage of manufacturing in China is that the quotas imposed by the E-Commerce Circular would not apply. Companies that establish a manufacturing base within China also avoid import duties.

However, Chinese consumers may find health foods and complementary medicines less appealing if these products are manufactured within China, even by a known international brand. This is partly due to the inherent distrust among Chinese consumers of Chinese-produced foods, supplements and medical items due to food safety scandals.

It may also be difficult to secure the cooperation or purchase control of a licensed manufacturer within China. Compliance issues are rife, and finding a compliant, appropriately licensed manufacturer may be difficult and a poor outcome could create a potential risk to a company's brand and reputation.

International companies that decide to manufacture food in China for the Chinese market must obtain a Food Manufacturing Licence. The general requirements for obtaining such a licence include:

- › having the appropriate site for processing, packing and storing the type and quantity of food
- › having the appropriate equipment and facilities for producing the food
- › employing food safety management personnel and complying with food safety regulations
- › having reasonable equipment layout and processing technology.



COMMON RISKS AND HOW TO AVOID THEM

Like all international commercial activities, exporting to and doing business in China carries certain risks. Proper preparation and mitigation strategies are essential to minimise these risks. Below are some key issues that Australian businesses may encounter and ways to mitigate them.

Trademarks

In China, trademark rights are derived from registration rather than use. In addition, China follows a 'first to file' principle, not 'first use'. Accordingly, the first party to file an application will generally be granted trademark rights.

Registration is inexpensive, from approximately US\$800 per mark. If an application goes smoothly without any objections or opposition, the process from filing to registration usually takes about a year.

Western brands are popular among pirates, trademark squatters and other entities in China. Australian companies that fail to register their brand as a trademark in China run the significant risk that another party will register it instead. This can be accomplished regardless of whether the products are the same as the original brand, whether the brand is used internationally, or any other consideration.

Prior use of an unregistered mark is rarely relevant. The only exception is if the mark is sufficiently well known to be protected under international conventions or Chinese trademark law. However, it is very unlikely an Australian brand would be judged sufficiently famous in China to gain this protection, so always register early and often, including Chinese versions of the trademark (see below for further information). Getting up-to-date professional advice for specific products and situations is also strongly recommended.

Both the Chinese Trademark Office and the Trademark Review and Adjudication Board (the trademark appellate division) are willing to consider oppositions and cancellations if it can be shown that a party has applied for a mark in bad faith. However, the problem – common in China – is that the criteria

for determining bad faith are not clearly delineated and it is hard to predict the outcome of claims.

As an example, King & Wood Mallesons China conducted a trademark search of the brands of 20 Australian retailers in China. The search showed 10 had no registration and 10 were registered. Of the 10 registered brands, seven had been registered by trademark squatters.

Chinese trademarks

A common and serious mistake made by international companies is failing to register Chinese versions of their trademarks. This can create a variety of problems.

Many companies assume they have no Chinese name unless they have created one themselves, but this is not the case. Most Chinese consumers cannot read English (or have limited English language skills) and tend to develop phonetic names for products based on their understanding of the international names.

Every product sold in China – from Coca-Cola to semiconductors – gains a Chinese version of its name. In some cases, the unofficial Chinese name becomes much better known than the official one. Examples include Pfizer's Viagra [official Chinese name: 万艾可 wan ai ke, unofficial name: 伟哥 wei ge] and Sony Ericsson [official Chinese name: 索尼爱立信 suo ni ai li xin, unofficial name: 索爱 suo ai].

For these reasons, Australian companies should be proactive and create a Chinese name that aligns with product and company brand values. This also allows companies to avoid 'doppelgängers' (Chinese versions of the product name which exist, but are not owned by the Australian company) from gaining a market foothold.

Beware of squatters

As more and more international companies enter the Chinese market, trademark squatters are increasingly registering Chinese names for products. Although it is generally possible to 'rebrand' the Chinese version of a product, it is likely to be expensive, create market confusion and delay building a business in China.

Working with distributors

Although this channel is not gaining as much media attention as cross-border e-commerce, nearly all international companies that wish to build a sizeable export market in China find themselves relying to some degree on distributors. When dealing with distributors, several issues are worth considering.

Avoid exclusive distribution deals

Be wary of assigning exclusivity for the entire China market, or even an entire province, to a single distributor as this can often restrict subsequent business development. If exclusivity cannot be avoided, then at least tie it to the distributor meeting certain targets.

Choose the right partner

Make sure to select the right distribution partner and ensure corporate cultures and business plans are compatible. It is also a good idea to independently verify a prospective distributor's background and check they have the capacity and expertise to store and distribute products.



Stay involved

Even if a distribution agreement is working well, Australian companies should maintain a high level of engagement with their distributor(s) to ensure their brand is being developed and supported properly, and is not being jeopardised by the actions of any distributor.

Have an exit plan

Put in place a termination or exit strategy before signing a contract to avoid getting caught in an unsatisfactory arrangement later on, especially if China has become a vital export market. Ensure any contracts provide a means to regain control of market distribution or, in the worst case, exit the market.

Advertising and labelling risks

Consumer rights are very much on the rise in China and failure to abide by the rules can be very costly. Chinese laws around advertising, as amended in 2015, impose significant restrictions on both advertising and labelling.

Advertising claims

Regardless of a product's quality, there are limits on what can be said to Chinese consumers about it. Major prohibitions on advertisements include:

- › providing false or misleading information which cannot be verified
- › using absolute or superlative terms such as 'highest grade', 'state-of-the-art', 'unique', 'best', 'first choice', 'top', 'favourite', 'the biggest' or 'No. 1'.

It is even prohibited to make references to awards won by a product or brand. When it comes to advertising in China, modesty counts.

In addition to advertising laws, complementary health products are subject to laws on food safety and other regulations that impose additional requirements around advertising and labelling. These include:

- › mandatory statements that the product is not a substitute for medicine
- › naming prohibitions
- › specifying the consumers for whom the product is suitable
- › instructions for use.

Health foods are prohibited from being compared to other supplements or drugs; from having wording that implies or asserts the product is necessary to maintain a level of health; or claims that the food prevents disease or can be used to treat a disease. 'Infomercial' or news release-style advertisements that are designed to resemble health and wellbeing information rather than being clearly identifiable as advertising are also prohibited.

Endorsements

Endorsements, which are often used by complementary medicines brands, are strictly regulated. The new Chinese Advertisement Law, which came into force in 2015, has specifically forbidden the use of endorsers to recommend or testify on behalf of health foods. As a workaround, some brands in these categories have used celebrities to endorse their brand rather than a specific product, but it is not yet clear whether this is permissible. Chinese law also requires the endorser to have actually used the product.

Food labelling

China's Food Safety Law sets strict requirements for labelling, including:

- › Chinese-language label requirements
- › font size specifications
- › expiry and production dates
- › ingredient list
- › weight
- › manufacturer and seller information.

The inclusion of a specific nutritional table is also mandatory and there are limits on the claims that can be made about nutritional content and effects.

Professional claimants

The introduction of consumer protection law has led to the rise of so-called 'professional fraud fighters' (PFFs). These are people, generally working in teams, who earn their living by purchasing goods with labels or advertising which breach the Chinese Advertising Law and then suing the seller for compensation. PFFs increasingly shop online.

Claims for breach can result in refund of monies paid, but also compensation of three to ten times the amount paid for the goods, depending on the breach. In addition, the compensation payouts and expenses associated with such litigation can be costly, especially if a company becomes a popular target. Complementary medicines face much tighter restrictions on advertising, labelling, product registration and filing, and are at high risk from attacks by PFFs.

FURTHER RESOURCES

Export readiness

To help companies determine whether their business is ready for exporting, Austrade has developed the [International Readiness Indicator](#), an online tool for prospective exporters.

Austrade has also prepared a general [Guide to exporting](#).

Austrade China's Health and Services team has also developed the 'China checklist' below based on general advice for Australian complementary medicines exporters considering the China market.

Professional advice

The regulatory and commercial environment in China is complex and subject to changes that can have significant implications for Australian exporters.

This guide is intended to provide only a general overview of systems and regulations at the time of publication in March 2017. Austrade strongly recommends Australian companies interested in exporting complementary medicines to China seek professional advice appropriate for their specific situation and products.

Below are a number of industry bodies that provide research and market access, product testing, clearance and regulatory compliance services in China. Please note this is not intended to be a comprehensive directory of providers.

Austrade can provide referrals to professional services firms and advisers that offer detailed assistance to help companies planning to export complementary medicines to China. For assistance in finding a service provider to assist with individual needs and arranging initial introductions, or advice on listing as a service provider with Austrade, please contact the Austrade China team at china@austrade.gov.au.

China checklist

- | | | |
|---|---|--------------------------|
| 1 | Register brand/trademark/IP/formula (if applicable) in China (English and Mandarin versions). | <input type="checkbox"/> |
| 2 | Develop Chinese labelling. | <input type="checkbox"/> |
| 3 | Develop a Chinese website or online store (if desired).
Identify an e-commerce partner or establish an e-commerce team with language, design and photo skills.
Refer to Austrade's E-commerce in China: A guide for Australian business . | <input type="checkbox"/> |
| 4 | Obtain a Blue Hat registration. | <input type="checkbox"/> |
| 5 | Identify a local importer/distributor. | <input type="checkbox"/> |
| 6 | Undertake a small batch trial shipment (recommended). | <input type="checkbox"/> |
| 7 | Obtain Australian made/owned/organic certification (if applicable/desired). | <input type="checkbox"/> |
| 8 | Develop online and offline pricing and promotion strategies. Obtain Australian made/owned/organic certification (if applicable/desired). | <input type="checkbox"/> |

King & Wood Mallesons

17/F, One ICC, Shanghai ICC
999 Middle Huai Hai Road, Xuhui District
Shanghai 200031

Phone: +86 21 2412 6000

Email: Mark Schaub – International Partner:
schaub@cn.kwm.com

Chen Bing – Partner:
chenbing@cn.kwm.com

Yang Yue – Managing Associate:
yangyue3@cn.kwm.com

Website: kwm.com

China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

12/F, No. 3 Building, Beijing INN,
No. 6 Nanzhuguan Hutong, Dongcheng District,
Beijing 100010

Phone: +86 10 5803 6332
(product registration)
+86 10 5803 6297 (trade events)

Email: info@cccmhpie.org.cn

Website: cccmhpie.org.cn

China Healthcare Association Health Food Market Working Committee

Room 902, Wanbo Commercial Mansion,
72 You'anmennei Avenue, Beijing 100054

Phone: +86 10 8350 5146
(research and information)
+86 10 8350 2445
(market access consultation)

Email: xiehui@chca.net.cn

Website: chca.net.cn

DISCLAIMER: Austrade does not endorse or guarantee the services of the organisations listed here. As the need for professional services varies depending on individual circumstances, please use commercial discretion to assess the suitability of these providers to meet your business needs. Austrade does not accept liability for any loss associated with the use of this information or the advice received from these organisations which are taken entirely at the user's discretion.

APPENDIX A: AUSTRALIAN CAPABILITY AND INDUSTRY/ GOVERNMENT ORGANISATIONS

Australia's complementary medicines industry has much to offer China: clean and safe products that align with Chinese needs, underpinned by comprehensive regulatory frameworks and a commitment to innovative research and development.

Complementary medicines, including health supplements and traditional medicines, have become an important part of Australia's health system. Uptake and demand from consumers in Australia and overseas have driven substantial industry growth in recent years. Revenues are projected to continue rising to A\$4.6 billion for 2017–18.³⁶

Overall sales of vitamins and dietary supplements grew by 19 per cent in 2013. Herbal or traditional product sales grew by eight per cent and sports nutrition by 14 per cent. Protein powders were the most popular sports products, with A\$272 million in sales and 67 per cent value share. Calming and sleep aid products such as passion flower and valerian also grew by 15.8 per cent over a five-year period, which may reflect growing demand from an ageing population.³⁷

Products that are promoted for specific health conditions are a growing trend, appealing to consumers by aligning more closely with their needs and simplifying the selection process. Many Australian complementary medicines manufacturers are also increasingly offering products based on TCM principles, which appeal to Chinese consumers, as does the use of natural ingredients.

Over 60 per cent of Australian complementary medicines companies are exporting. Complementary medicines exports are growing at a faster rate than domestic sales. IBISWorld reports that 26.6 per cent of industry revenue was derived from exports in 2010–11 and predicts this proportion to reach 42.1 per cent by 2020–21. Vitamin and supplement exports were worth an estimated A\$365 million in 2015–16.³⁸

In 2014, Australia exported complementary medicines to 26 countries. The top five markets were New Zealand (61 per cent), Singapore (38 per cent), Hong Kong (36 per cent), Malaysia (29 per cent) and China (26 per cent).³⁹ China is Australia's second largest market for pharmaceuticals overall, with exports (including vitamins and health products) worth A\$381 million in 2013–14.⁴⁰ Australia's share of the Chinese complementary medicines market was 14.3 per cent in 2016.⁴¹

Key industry capabilities and strengths

There are around 70 premises licensed by the Therapeutic Goods Administration (TGA) to manufacture complementary medicines in Australia, predominantly in New South Wales, Victoria and Queensland. Many of these companies also produce OTC products.

Australia's complementary medicines industry is underpinned by a regulatory regime that is regarded as one of the strongest in the world. Products are manufactured to a pharmaceutical standard under Good Manufacturing Practice, and the TGA enforces strict safety and quality regulations.

This robust regulatory environment helps place Australia in a strong competitive position as an exporter of complementary medicines. Australian complementary medicines have a strong reputation among Chinese consumers, thanks to Australia's 'clean, green and safe' national image and its reputation for premium-quality products and a well-regulated manufacturing environment.

Research centres and collaborations

Australia is home to a number of complementary medicines research centres.

The National Institute of Complementary Medicine (NICM) conducts clinical and laboratory research to close the gap between the use of complementary medicines and understanding and knowing how they work. NICM's clinical trial work focuses on women's health, aged care, cardiovascular health and gastroenterology. Its pre-clinical laboratory research focuses on identification, bioactivity and the action mechanisms of herbal medicines and herb–drug interactions.

The Australian Research Centre in Complementary and Integrative Medicine researches the use of complementary medicines in Australia with direct relevance to patient care and health policy. Areas of

focus include women's health, especially for pregnancy, back pain, cancer care and allergies, palliative care, chronic illness and ageing.

The Chinese Medicine Confucius Institute, a collaboration between RMIT and Nanjing University of Chinese Medicine, is a leader in the development of TCM education in the Western world.

Industry and government organisations

The following are some of the organisations involved in the Australian complementary medicines industry.

Therapeutic Goods Administration

The Therapeutic Goods Administration is part of the federal Department of Health and is Australia's regulatory authority for therapeutic goods.

tga.gov.au

Australian Self Medication Industry

The Australian Self Medication Industry is the peak body representing companies involved in manufacturing and distributing non-prescription consumer healthcare products in Australia. It also represents related businesses, including advertising, public relations, legal, statistical and regulatory consultancy companies and individuals.

asmi.com.au

Complementary Medicines Australia

Complementary Medicines Australia represents the complementary healthcare products industry. Its membership includes importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multilevel marketers and consumers.

cmaustralia.org.au

HOW AUSTRADE CAN HELP

The Australian Trade and Investment Commission – Austrade – contributes to Australia’s economic prosperity by helping Australian businesses, education institutions, tourism operators, governments and citizens as they:

- › develop international markets
- › win productive foreign direct investment
- › promote international education
- › strengthen Australia’s tourism industry
- › seek consular and passport services.

Austrade provides information and advice that can help you reduce the time, cost and risk of exporting. Austrade offers a range of services to Australian exporters in growth and emerging markets.

Austrade in China

Austrade maintains a network of 10 offices throughout mainland China. Austrade’s Chinese-speaking staff can provide exporters with market guidance and access to information, promotions and referrals. Austrade works with industry to promote Australian capabilities in China, showcasing Australian expertise at ministerial business missions and Australia–China forums and seminars. Austrade also runs inbound trade missions and supports Australian businesses to attend local industry and business exhibitions across China.

Contact Austrade for more information.

austrade.gov.au
info@austrade.gov.au

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