

1. INTRODUCTION

China's healthcare market is predicted to be worth GBP 46.2 billion by 2020. An ageing population, a growing middle class, lifestyle changes, air pollution concerns, and increasing awareness of the importance of good health are some of the growth drivers that companies in, or planning to enter, the Chinese market need to consider when effectively building and implementing a long-term strategy. To maximise opportunities, companies must be equipped to tackle any problems that arise, adequately operate within the law, and familiarise themselves with the Chinese market.



2. CLASSIFICATION

There are two general food classifications in China:

- General food products (一般食品);
- Health food products (保健食品).

International food product companies may sometimes be uncertain whether or not their products should be registered as health food products. As China's **Food Safety Law** (食品安全法) states, general food products can be either finished products or raw materials made for human consumption, and include both food products and traditional Chinese medicines. However, products that are made to cure diseases are not classed as general food products.

In addition, the China Food and Drug Administration (国家食品药品监督管理总局, "CFDA") states that "Health food products are in a special category of food products, in between other food products and drugs.

- "Health food products emphasise the health benefits of the product in question, whereas other food products emphasise the product's nutritional information;
- "Health food products have dosage instructions, whereas other food products do not;
- 3. "Based on its individual properties, each health food product is particularly suited or unsuited to different groups of people, whereas other food products are not."

In March 2018, the **State Administration of Market Regulation** (国家市场监督管理总局, "SAMR") replaced the CFDA, meaning the CFDA's responsibilities and jurisdictions referred to in this report are now performed by the SAMR, although are still sometimes referred to as being carried out by the CFDA.

3. CHINESE AND INTERNATIONAL DEFINITIONS

Health food products in China fall into two categories:

• Functional health food products (功能性食品)

Functional health food products are food products that the manufacturer claims have specific health functions. This refers to food products most suitable for consumption by specific types of people, and that regulate bodily functions, but do not treat diseases. CFDA-certified functional health food products can have a Blue Hat logo (蓝帽) on their packaging, hence functional health food products are sometimes referred to as "Blue Hat products".

• Nutritional supplements (膳食补充剂)

Nutritional supplements are supplements in which vitamins and minerals are the main active ingredients.

Only a relatively small proportion of the different types of vitamins, minerals, and food additives are considered to be nutritional supplements.

In addition, there are other categories of food in China, including special dietary food products, which include food for special medical purposes (医用食品) ("FSMP"). FSMP has different CFDA registration procedures, as well as different sales and marketing channels.

Sports nutrition food products (运动功能食品) are also a type of special dietary food product, and are classed as general food products about which the manufacturers make certain nutritional claims of being suitable for people that partake in sport.

4. MARKET BARRIERS: REGISTRATION AND ADVERTISEMENT LAW

The Chinese market presents significant opportunities for companies operating in the nutritional supplements industry. However, the market is heavily regulated, with high barriers to entry and certain impediments to success.

Barriers to entry include product registration requirements, regulatory compliance, intellectual property infringement, the complexity and uncertainty regarding the laws affecting the industry, restrictions on advertising, and a number of other issues, as would be expected in a large and dynamic market.

Following a series of food scandals, in 2015 the Chinese government began to implement stricter food safety laws. These laws had a significant impact on the health food industry, including requiring registration of health food products sold to, and within, China, and restrictions on the advertising of health food products.

Most health food companies from western countries selling their products in China do so through cross-border E-commerce.

This can either be done through a company's online store or on platforms such as Tmall, JD.com, or Amazon.

In April 2016, as part of the Food Safety Law the Chinese government issued a new set of regulations requiring all health food products sold to and within China to comply fully with Chinese regulations by the end of 2017. Distributors of health food products that did not comply fully with regulations by this time risked being fined or being banned from the market. This means there are now strict laws on health food product advertising, including on printed advertisements and online marketing on websites and social media. In response, leading search engines, social media providers, and E-commerce companies such as Baidu, Weibo, and Alibaba employed additional staff to comply with the new advertising regulations, and some companies have since dropped advertisements which do not comply with this new set of regulations.

5. INGREDIENT SCREENING AND LABELLING OF NUTRITIONAL SUPPLEMENTS

For food products sold to or within China, the process starts with screening the ingredients and intake levels. All ingredients must be classed as either general food raw materials, general food additives, general food nutrition enhancers, or as being compliant with special regulations, and the content should be within the recommended daily intake levels.

Documentation and certification of the source of certain raw materials is required for the importation of general food products, including special dietary food products, while for general food products and sports nutrition food products there are special regulations covering the functional claims allowed on the labelling.

Nutrient reference values ("NRVs") for sports nutrition food products are calculated in the same way that they are in health food products,

and should be included on to the labelling, along with the ingredients list, manufacturer's details, Chinese distributor's details, and production date in Chinese.

Certain supplements can be imported into China as special dietary food products or sports nutrition food products, instead of the importer applying for a CFDA certificate. All ingredients used in these supplements must be classed as general food products and no functional health claim can be used in the marketing and sales of the supplements. Sports nutrition food products and products with weight management properties are often suited to this importation category in China, and if there is already documented demand for the product in question in China, applying for a Blue Hat certificate is recommended, as it would allow the use of a stronger functional claim, such as a claim of "weight loss" or "alleviates physical fatigue".



6. APPLICATION PROCEDURE AND TIMING

The CFDA certificate application process can take two to four years, but companies can significantly speed this up if they provide the necessary ingredients list, manufacturing process information, company information, and sales documentation in a timely manner. Some documents must be ordered in advance, therefore while work is ongoing on the ingredient screening and modification of the formulas, assembly and preparation of the documentation needed

for the application for health food product classification should also be in progress.

It is crucial that the application materials include all documents required by the CFDA. Failure to do so risks the application being denied, and the CFDA states that inadequate applications can only be resubmitted once.

7. DISTRIBUTION AND MANUFACTURING IN CHINA

Finding the right distribution channel is a key part of a company's success. Most international companies intending to sell health food products in China adopt one or a combination of the following models:

• General Trade: Through Chinese Importers and/or Distributors

The most common approach to importing health food products into China is via the general trade model. Products are imported into China through regular inspection and quarantine ("I&Q") and customs channels. Engaging a distributor or establishing a wholly foreign-owned enterprise (外商投资企业, "WFOE") to import and distribute 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 Guo Biao Standards (国标, "GB Standards"). There is a CBBC and Knudsen&CRC report containing more details about health food product filling and registration requirements.

Cross-Border E-Commerce (Including the Direct Shipping Model and the Bonded Zone Model)

In March 2016, Chinese authorities issued a Circular on Tax Policy for E-Commerce Retail Imports (关于跨境电子商务零售进口税收政策的通知, the "E-Commerce Circular"), followed by two Cross-Border E-Commerce Retail Lists of Imported Goods (跨境电子商务零售进口商品清单, "the Positive List") in April 2016. These new rules created a new regulatory and supervision regime for cross-border E-commerce. The new system has four main pillars:

- Products must be on the Positive List to qualify for cross-border e-commerce;
- 2. Health food products must have appropriate registration or filing under Chinese law;
- 3. The seller's website must be connected to Chinese Customs or provide detailed electronic information, including transaction, payment, and logistics information;
- 4. Products sold via cross-border e-commerce channels are subject to a new tax system.

Postal Route

Postal purchases are considered a personal import and not included in the E-Commerce Circular. A common model used for postal purchases is consumer-to-consumer ("C2C") sellers, who buy products in other countries (often western countries) and sell them to Chinese consumers via online platforms such as Taobao. This is known by its Chinese name: the daigou (代购) model. The postal route is not intended to be used for shipping commercial quantities, so is susceptible to government crackdowns. It is not an official channel for E-commerce, therefore goods sent in this way are not eligible for expedited inspection, nor are they subject to quarantine or customs clearance processes. However, Chinese customers are responsible for paying tax on the product purchased and making any necessary tax declarations, and they face restrictions on the value of items that can be imported.

To avoid being limited by quotas and to get closer to the market, some companies initiate manufacturing in China. There are cases of mainland Chinese or Hong Kong companies investing in or buying international health food product companies, so as to allow the products made by these companies to have better access to the China market.

International companies that sell large quantities of their products may find general trade or China-based manufacturing more attractive than cross-border imports, or may find that a mix of models is most suitable.

One advantage of manufacturing in China is the avoidance of E-Commerce Circular quotas and import duties. However, Chinese consumers have a relatively high level of distrust of Chinese-made products, so they could find health food products that are manufactured in China less appealing than if these products had been manufactured internationally, even if the product in question is the same in all other ways. Other drawbacks to manufacturing in China include the difficulty of securing cooperation from a licensed manufacturer, compliance issues, and the unsatisfactory production of goods, all of which can negatively impact a company's brand and reputation.

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8. APPENDIX

- State Administration of Market Regulation (国家市场监督管理总局, "SAMR");
- China Food and Drug Administration (国家食品药品监督管理总局, "CFDA");
- Food for Special Medical Purpose (医用食品, "FSMP"); Food that benefits patients recovering from medical conditions;
- Nutrient Reference Values ("NRVs"); The scientifically recommended quantity of nutrients;
- Guo Biao Standards (国标, "GB Standards"); National standards in China that protect health and personal property and ensure safety; all products and services must comply with national standards and products being sold in China undergo tests to ensure they meet GB standards;
- Daigou (代购); An agent that purchases products outside of China and sell them to consumers in China.

For further enquiries and help with exporting sports nutrition products to China please contact Mette Knudsen at: Mette@knudsenchina.com or Ran Guo at: Ran.guo@cbbc.org.cn.

