Practical Law™

GLOBAL GUIDE 2021
COMMERCIALISATION OF HEALTHCARE

Commercialisation of Healthcare in China: Overview

Alan Zhou, Charlene Huang and Samantha He, Global Law Office

global.practicallaw.com/1-617-8421

MEDICINES

1. What is the definition of medicine (or equivalent) in your jurisdiction?

The *Drug Administration Law* (2019 Revision) (DAL), together with its implementing rules, formulates the fundamental legal framework for the administration of drug-related activities, including drug development, registration, manufacture, and distribution.

The DAL defines a "drug" as a substance that is used to prevent, treat, or diagnose human diseases and is intended to regulate human physiological functions, for which usage and dosage are specified for indication/primary treatment. Under the DAL, drugs are categorised into three types:

- Traditional Chinese medicines.
- Chemical drugs.
- Biological products.

Chinese medicines are governed by the *Traditional Medicine and Drug Law* (with effect from 2017). Unless otherwise specified, drugs discussed in this Q&A refer to chemical drugs and biological products.

2. What authorities are responsible for regulating the manufacture, marketing and advertising of medicines?

Activities related to drug research and development (R&D), registration, manufacture, distribution, advertisement, and promotion are regulated by the following authorities:

- **State Administration for Market Regulation (SAMR).** The SAMR is the national authority for market supervision, among other things, in the areas of anti-monopoly, product quality safety, intellectual property (IP), fair competition, general advertising enforcement, and commercial bribery.
- **National Medical Products Administration (NMPA).** The NMPA is a national bureau operating under the supervision of the SAMR. It is involved in the administration of all aspects of drug R&D, registration, manufacture, and distribution, and formulates rules and national standards related to drugs. It (and its delegated local counterparts) has the authority to issue relevant permits such as market authorisation for drugs, manufacturing licences, distribution licences, and drug advertising permits.
- **National Health Commission (NHC).** The NHC is mainly responsible for national health policies, the reform of the medical and health care system, disease prevention and control, and the national essential drug system (that is a system that effectively manages the selection, production, circulation, use, pricing, reimbursement, monitoring, and evaluation of essential drugs, and is linked to the public health, medical services, and medical security systems). The NHC also supervises the National Administration of Traditional Chinese Medicine.
- **National Healthcare Security Administration (NHSA).** The NHSA is mainly responsible for preparing and implementing regulations and policies related to basic state medical insurance, including policies regarding reimbursement, pricing, and procurement of drugs.

These national authorities generally delegate part of their authority to local counterparts, to carry out administrative enforcement activities within the jurisdiction.

3. What notifications, registrations, approvals and licences are required to manufacture and market medicines and their active pharmaceutical ingredients?

Authorisation

Before a drug is launched on the market, it must receive market authorisation from the NMPA. Depending on the drug's authorisation status, there are three types of authorisation applications:

- **Initial registration.** This is generally the required route when a specific drug is to be marketed in China. The application must be made to the NMPA's Centre for Drug Evaluation (CDE). The CDE conducts a comprehensive check of the active pharmaceutical ingredients of the specific drug when reviewing the drug registration application. Once the application has been authorised, the applicant receives a drug registration certificate and becomes a market authorisation holder (MAH). A MAH must take responsibility for the drug over its whole "lifecycle," including regarding pre-clinical studies, clinical trials, manufacture and operation, post-marketing studies, supervision of any adverse reactions, and relevant reporting requirements (*DAL*).
- **Re-registration application.** An application to renew a valid drug registration certificate must be filed be filed six months before the expiration of the five-year term of the initial certification.
- **Supplemental application.** A supplemental application is generally required when there are changes to drugs with an existing drug registration certificate (for example, changes related to drug safety and efficacy on the instructions, or a change of MAH).

Drugs without market authorisation can be administered to patients in certain circumstances. For example, the DAL explicitly permits compassionate use allowing physicians and patients access to pre-approval investigational drugs if the drug:

- Is being clinically trialled.

- Is being used for a disease that threatens life but lacks effective alternative treatment.
- Is potentially effective, based on medical observations.
- Is used in compliance with ethical principles.
- Usage in this context has been reviewed by the ethics committee and the patient's informed consent has been obtained.
- Is used only within the clinical trial site and on patients outside the clinical trial setting but with similar conditions.

The DAL also provides exemptions from market authorisation for the importation of:

- A small number of drugs by a medical institution due to specific urgent clinical needs.
- A small number of drugs brought into China by an individual for personal medical use.

(*See Question 7.*)

Manufacturing

Drug manufacturing plants must obtain drug manufacturing licences from provincial MPAs. MAHs which lack manufacturing capacity can outsource the manufacturing work to third parties with manufacturing capabilities and licences. A manufacturing licence is valid for five years, and renewable for another five years six months before expiry.

Marketing

Drug distribution requires a valid drug distribution licence. A distributor must apply to the relevant provincial MPA for a wholesale drug distribution licence if selling to entities, or apply to the relevant municipal MPA for a retail drug distribution licence if selling to individual consumers.

The online sale of drugs is permitted, except for special types of drugs such as:

- Vaccines.
- Blood products.
- Narcotic drugs.
- Psychiatric drugs.
- Toxic drugs for medical uses.
- Radioactive drugs.
- Pharmaceutical precursor chemicals.

The drug distribution licence is valid for five years, and is renewable six months before expiry.

4. What are the differences between the regulation of new innovative medicines and generic or biosimilar versions of those medicines?

Generally, the DAL applies to both innovative drugs and generic/biosimilar drugs. However, the registration process (*see Question 3*) for an innovative drug tends to be more complex and longer than that of a generic/biosimilar drug. For example:

- Innovative drugs must always be subject to clinical trial before an authorisation application can be made, whereas generic drugs and in vitro diagnostic reagents may not need to undergo clinical trials, and therefore authorisation can be sought immediately.
- Generic drugs may be, subject to the CDE's evaluation, exempted from onsite inspection of manufacturing premises during the registration process, whereas onsite inspection of the manufacturing premises is generally required for innovative drugs.

(*Measures for the Administration of Drug Registration.*)

5. What are the differences between the regulation of prescription and over-the-counter medicines?

The DAL classifies drugs as either prescription drugs and non-prescription (over-the-counter (OTC)) drugs, which are regulated differently. A patient must present a prescription when purchasing prescription drugs, while OTC drugs can be bought without a prescription. China further subdivides OTC drugs into Class A and Class B, with Class B OTC drugs being subject to higher safety standards.

6. Are there fewer or different requirements for the approval of medicines that have already been licensed or approved in another jurisdiction?

Generally, drugs licensed or approved in another jurisdiction must be registered with, and authorised by, the CDE before being imported into China (*see Question 3*). Certain preferential treatments apply, for example:

- **Procedure for review and approval.** If the drug that has been marketed outside China is on the CDE's list of overseas new drugs urgently needed for clinical use, the applicant can request priority review of the drug registration, and the CDE can radically shorten the review period.
- **Clinical trial requirement.** Clinical trial data generated outside China can be cited in support of the drug registration application, and in certain circumstances further clinical trials within the PRC may not be required.

7. Is it possible to sell medicines to or buy medicines from other jurisdictions?

Imports

It is legally permissible to import drugs into China, except for special situations expressly regulated by the DAL (for example, a special permit is required to import narcotic drugs and psychiatric drugs). When importing drugs into China, the following key regulatory requirements apply:

- The MAH must obtain an imported drug registration certificate (see *Question 3* for the situations where an application to register for authorisation is not required).
- The importer must file a drug import record with the local medical products association (MPA).
- The importer must register as a foreign trade operator with its local commerce bureau.
- The customs authorities must review the imported drugs and documents, and the importer must pay customs tariffs.

Failure to comply with these regulatory requirements can lead to consequences including fines, confiscation of illegal gains, suspension of operation, or revocation of relevant approval. Serious offences may trigger criminal liability.

An importing enterprise should also be aware of the issue of parallel imports (that is, importation of genuine goods that have been lawfully manufactured and marketed abroad, or where the importer has obtained the consent of the patent holder but not the

authorisation of the exclusive licensee in China). The *Trade Mark 1982* (revised in 2013) *Law* does not expressly restrict the import and distribution of non-counterfeit and genuine products from other markets; however, previous case law indicates that parallel imports may constituted trade mark infringement if the trade mark owner's reputation is damaged by the importation. It is generally understood that (under the *Patent Law 1992*) patent infringement cannot be established in the case of parallel imports.

Exports

The export of drugs is allowed, except for special situations expressly regulated by the DAL. Narcotic drugs and psychiatric drugs are generally subject to a special export permit. The export of drugs included in the CDE's list of overseas new drugs urgently needed for clinical use can be restricted in the interests of public welfare.

8. How is medicine promotion and advertising activity regulated, and what are the general requirements to advertise medicines?

One of the main laws regulating advertising activities is the *Advertising Law* (revised in 2021), which imposes regulatory requirements on all types of advertisements.

Promotional activities that do not constitute advertising are regulated by the *Anti-Unfair Competition Law* (revised in 2019), the *Consumer Rights and Interests Protection Law* (revised in 2014), and other laws and regulations.

The advertising of drugs, in particular, is further regulated by the:

- DAL.
- Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Foods and Formula Foods for Special Medical Purposes.

These detail the approval procedures, contents and other regulatory requirements for drug advertisements, including:

- **Prior approval.** Drug advertisements must be examined and approved by the relevant provincial MPA or its designated counterparts before publication. Prior approval is not required if the advertisement only refers to the drug name, but not other aspects such as its efficacy and safety.
- **Prohibition on advertising.** Certain categories of drugs are entirely prohibited from being advertised, including narcotic drugs, psychiatric drugs, toxic drugs for medical use, and radioactive drugs.
- **Contents of advertisement.** As well complying with the general regulatory requirements of the *Advertising Law*, the contents of drug advertisements must also comply with specific requirements, for example:
  - not using the names or images of academic institutions or experts to endorse drug efficacy; and
  - not including misleading statements that a drug can cure all diseases.
- **Advertising channels.** OTC drugs can be advertised to the general public, but prescription drugs can only be advertised in a pharmaceutical or medical journal aimed at qualified professionals.

9. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

The DAL generally applies to all types of drugs, but there are specific rules and regulations that contain additional regulations for specific types of drugs. For example:

- The R&D, registration, manufacturing, and distribution of vaccines is regulated by the *Vaccine Administration Law* (with effect from 2019).
- Blood products (drugs made of a variety of human plasma protein products) are governed by the *Regulations on the Administration of Blood Products*.

There are no specific regulations for drugs intended for rare diseases, paediatric drugs, and cell therapy drugs. However, administrative technical guidance and codes are published to provide applicants with guidance on the conduct of R&D and registration for authorisation (*see Question 3*) in these areas.

10. What controls apply to medicines or components of medicines that derive from humans or animals or incorporate modified genetic material?

Drugs Derived from Humans

In addition to the DAL and its implementing rules, which apply generally to all types of drugs, drugs that derive from humans or incorporate modified genetic material are subject to the *Bio-Security Law* (with effect from 2021) and the *Administrative Regulations on Human Genetic Resources* (with effect from 2019) (HGR Regulations).

Human genetic resources (HGR). Both HGR materials (that is, tissues, cells, and others that contain hereditary substances) and HGR information (information that is generated from HGR materials) are regulated by the HGR Regulations and the Bio-Security Law. Both Chinese and foreign entities/individuals must comply with the HGR requirements when using HGR. Further, a foreign entity that wished to develop drugs by using HGR must co-operate with a Chinese partner and apply for the approval or filing of such co-operation.

Foreign investment. Foreign investors cannot invest in the development and application of human stem cells and gene diagnosis and treatment technologies (*Special Administrative Measures (Negative List) for Foreign Investment Access (Edition 2020)*).

Specific products. Specific products may be subject to further regulatory requirements. For example, under the *Regulations on the Administration of Blood Products*, a blood product manufacturer can only collect source plasma from a plasma collection station that has a licence for plasma collection.

Drugs Derived from Animals

In addition to the generally applicable laws and regulations, the R&D, manufacture and other activities relating to drugs that derive from animals must comply with the *Bio-Security Law*, regulations relating to animal protection and animal welfare, and certain technical requirements. For example:

- Certain animal parts cannot be used in drug manufacturing (such as rhinoceros horn and tiger bone), subject to limited exceptions.
- Animal welfare must be taken into consideration in all relevant activities. For example, the Good Laboratory Practices for Non-Clinical Drug Research, published by the China Food and Drug

Administration (now NMPA) in 2017, provides that when using experiment animals, the principle of "reduction, replacement and refinement" must be followed. This implies:

- using methods or strategies that replace or avoid the use of animals in research and testing;
- reducing the number of animals used to achieve scientific objectives, for example, by improving experimental design and statistical analyses; and
- refining scientific procedures and other factors affecting animals (for example transport, housing, restraint) to reduce suffering and improve animal welfare at all stages of their lives.

- Technical requirements specific to drugs deriving from animals must be adhered to, including the *Biological and Chemical Drugs Annex* to the *Good Manufacturing Practice for Drugs* (published by the NMPA).

BIOLOGICAL MEDICINES

11. What is the definition of biological medicines in your jurisdiction and what are the main laws that specifically apply to them (if any)?

According to the NMPA's *Registration Classification and Declaration Requirements for Biological Products 2020*, "biological products" are defined as preparations made from microorganisms, cells, animal or human tissue or body fluid via biological techniques, for the purpose of prevention, treatment, or diagnosis of human diseases.

12. Are there any additional or alternative regulations that apply specifically to biological medicines?

In addition to the market authorisation requirements which apply to all drugs (*see Question 3*), biological products are subject to some special provisions. For example, in addition to a market authorisation, the MAH of the biological products must obtain a batch release certificate for the release of a batch before distributing the product.

MEDICAL DEVICES

13. What is the definition of medical device (or equivalent) in your jurisdiction? What is the significance of any legal classifications?

Under the *Regulation on the Supervision and Administration of Medical Devices* (revised in 2021), the term "medical device" refers to instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials, and other similar or related articles (including computer software) that can be used directly or indirectly with human bodies to achieve specified purposes (such as diagnosis, prevention, and monitoring).

Unlike medicines, the effectiveness of medical devices is primarily achieved by physical or other similar means rather than by pharmacological, immunological, or metabolic means (or where non-physical means only have auxiliary functions).

The *Regulations for the Supervision and Administration of Medical Devices* (revised in 2021) (RSAMD) classify medical devices into Class I, Class II, and Class III, according to their risk levels and expected purposes, structural features, methods of use, and other qualities. Class III medical devices are those with the highest risk level, and their safety and effectiveness is subject to strict regulation.

The NMPA has significant discretion to determine whether a substance constitutes a drug, a medical device, or is subject to another regulatory regime. The NMPA and experts from the CDE or Centre for Medical Device Evaluation (CMDE) (or both) will decide on whether to regulate a product as a drug or device.

Subject to the CMDE's review, mobile applications can be registered as medical devices.

14. What authorities are responsible for regulating the manufacture, marketing and advertising of medical devices?

Similar to the governing system for drugs, the R&D, registration for authorisation/filing (*see Question 15*), manufacture, distribution, post-marketing risk management and advertising of medical devices are subject to administration by the SAMR, NMPA (and its affiliate CMDE), NHC, and their local counterparts (*see Question 2*).

15. What notifications, registrations, approvals and licences are required to manufacture and market medical devices?

Product Registration/Filing Requirements

Before launching a medical device on the market:

- Details of Class I medical devices must be filed.
- Class II and III medical devices must be authorised and granted medical device registration licences.

(*RSAMD.*)

(Applicants both for filing records and for medical device registration licences are referred to here as the MAH.)

Depending on the status of the medical device, there are three types of registration/filing application:

- **Registration/filing application.** This is generally required when a specific medical device is to be marketed in China:
  - details of Class I devices must be filed with the municipal MPA (for domestic devices) or the NMPA (for imported devices); and
  - Class II and III devices must be registered with, and authorised by, the municipal MPA (for domestic Class II devices) or the NMPA (for domestic Class III and imported Class II and III devices).
- Priority review may be available for urgent clinical need medical devices and innovative medical devices.
- **Renewal application.** This is required when renewing a valid Class II and Class III medical device market authorisation; it must be filed at least six months before the expiry of the existing authorisation. A Class I filing record does not need to be renewed, unless otherwise required by law.
- **Supplemental application.** This is required when there are material changes to Class II and Class III medical devices with existing market authorisation (for example, changes in design, raw materials, manufacturing technology, or scope of application) which could affect the safety and efficacy of the medical device. Other non-material changes must be reported to the relevant authorities, but do not require an application for approval.

Medical devices without a registration licence/filing record can be used on patients in some circumstances permitted by law. For example, the RSAMD permit:

- Compassionate use, allowing physicians and patients access to pre-approval investigational medical devices.
- Import of a small number of medical devices by a medical institution due to specific urgent clinical need.

Manufacturing

Different types of medical devices require different manufacturing licences/filing records:

- Class I medical devices: the manufacturer must submit a filing to the municipal MPA, and the MPA immediately provides a filing record if all required documents are submitted. A filing receipt for Class I devices does not specify the duration of authorisation.
- Class II and III devices: a manufacturing licence is granted by the NMPA following a successful review and site inspection. A manufacturing licence for Class II and III devices is valid for five years and can be renewed for another five years before expiry.

Marketing

The marketing requirements are as follows:

- Distribution of Class I medical devices: this does not require a special licence/filing record.
- Distribution of Class II medical devices: a distributor must maintain a distribution filing record at the municipal MPA, unless otherwise exempted by law. A filing record for Class II devices does not specify a validity period.
- Distribution of Class III devices: this requires a distribution licence from the municipal MPA. A distribution licence for Class III devices is valid for five years and can be renewed for another five years before expiry.

16. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

Medical devices that have been approved in another jurisdiction can be imported into China after they have received either a filing record for a Class I medical device, or a medical device registration licence for a Class II or III medical device (*see Question 15*). Clinical trial data obtained abroad can be used in the registration application/filing for that medical device in China.

Under the 14th Five-Year Plan (2021-2025) for National Economic and Social Development and the Long-Range Objectives Through to the Year 2035, policies will further facilitate the domestic authorisation of medical devices that have been approved in another jurisdiction.

17. Is it possible to sell devices to or buy devices from other jurisdictions?

Imports

Generally, it is legally feasible to import medical devices if the following requirements are met before importation:

- Filing or registration with the NMPA (*see Question 15*).
- Filing of a relevant import report with Customs, and payment of the appropriate tariff.
- Registration of the importer as a foreign trade operator.
- For certain medical devices, China compulsory certification (3C), which certifies that the products meet the standards set by China.

Exports

The export of medical devices is permitted. The exporter must:

- Ensure that the exported medical devices meet the requirements issued by the importing country/regions.
- File information regarding the export of those devices with the municipal MPA at the manufacturer's location.

18. What are the general requirements to advertise medical devices?

Other than the regulatory requirements and restrictions applicable to all types of advertisements (*see Question 8*), the main additional requirements regarding the advertising of medical devices are that:

- The advertisement's content must be in line with its product registration certificate/filing notice (*see Question 15*), label, and instructions.
- The advertisement must not contain any assertion or guarantee about the device's efficacy, safety or curative rate, nor any comparison with other medical devices, recommendation, and/or endorsement of an advertising spokesperson, among other things.
- Advertisements for medical devices must not be published on mass media targeted at minors.

19. What product marking is required for authorised medical devices?

The content of the instruction and label of the product must be in line with that registered or filed with relevant MPAs (*RSAMD*) (*see Question 18*). Imported medical devices must have instructions and labels attached in Chinese, indicating the place of origin, the foreign MAH and its domestic agent, along with relevant contact information. The instructions and labels must also comply with requirements set out in other regulations, such as the *Administrative Rules on Instruction Manuals and Labels of Medical Devices*.

There are plans for the NMPA to operate a unique device identification (UDI) system for medical devices, under the RSAMD. The UDI would enable product identification and manufacturing identification, and is designed to enable the tracing and recording of the distribution flow of medical devices. The NMPA intends to implement the UDI system gradually, and the implementing rules are currently under discussion.

COMBINATION PRODUCTS

20. Does your jurisdiction recognise combination products? What are the main laws that specifically apply to them (if any)?

If a product is a combination product (that is, it contains more than one type of product, such as a drug and a device), its classification is determined according to the principles in the *Notice of Matters Related to Registration of Combination Products*:

- When there is a similar product on the market, the NMPA generally follows the recognition standard precedent for registration, and categorises the product as a drug or medical device.
- When no similar products are registered on the market, the applicant must apply to the NMPA for product attribute identification, and, based on the NMPA's decision, register the product as either a drug or a medical device.

Once classified, the product is governed by the laws that apply to the relevant class.

21. Are there any additional or alternative regulations that apply specifically to combination products?

No additional or alternative regulations specifically apply to combination products (*see Question 20*).

NATURAL HEALTH PRODUCTS

22. Is there a category for natural health products (or equivalent) (including, for example, traditional medicines, homeopathic medicines, supplements, vitamins and minerals)?

Special foods can be classified, depending on their nature, as:

- Foods for special medical purposes (FSMP), which are specifically processed and prepared foods for special needs of the population groups with eating restrictions, disorders of digestion and absorption, metabolic disorders, or special diseases with respect to nutrients or diets.
- Health foods, which are foods with specific health functions or for the purpose of supplementing vitamins and minerals, which are suitable for special population groups to eat, have functions of regulating the body, are not aimed at curing diseases, and will not cause any acute, sub-acute or chronic harm to the human body. (Depending on the nature, use, purpose, and formulation of vitamins and minerals, they could be registered either as health foods or drugs.)

FSMP, health foods or other foods must not be used as drugs or promoted as having drug efficacy.

Traditional Chinese medicines (TCMs) are classified as a type drug under Chinese law (*see Question 1*). TCMs are subject to the general laws and regulations applicable to drugs as well as special requirements.

23. What authorities are responsible for regulating the manufacture, marketing and advertising of natural health products?

Generally, the registration/filing, manufacture, distribution and advertising of health foods and FSMP are regulated by the SAMR and its local counterparts:

- **Advertising.** The SAMR sets rules and policies at the national level, while the provincial AMR is responsible for regulatory enforcement, including pre-approving advertising and penalising illegal advertisements.
- **Product registration/filing.**
  - health foods using ingredients outside the health food ingredient list and health foods that are imported in China for the first time are regulated by the SAMR; other health foods are regulated by the provincial AMR; and
  - FSMP are regulated by the SAMR.
- **Manufacturing.** Manufacturing licences for health foods and FSMP are issued by the provincial AMR.
- **Distribution.** The local AMR at or above the county level is responsible for the issue of distribution licences for health foods and FSMP.

24. What notifications, registrations, approvals and licences are required to manufacture and market natural health products?

Registration/Filing

Before health foods or FSMP are launched on the market, they must be either:

- Filed with the provincial AMR: for supplements, vitamins and mineral nutrients that are imported in China for the first time, and health foods that use ingredients on the ingredient list issued by NMPA.
- Registered with the SAMR: for FSMP, other health foods that are imported in China for the first time, and health foods that use ingredients outside the ingredient list issued by NMPA.

The applicant may need to submit the following:

- Application form.
- Product R&D report.
- Formulation information.
- Details of materials used in the production process.
- Assessment report regarding food safety and health.
- Product packaging information, label, instructions, and samples.
- Any other items required by the AMR.

Manufacturing

After making the required filing or registration as discussed above, the applicant can apply for a food manufacturing licence. The application procedure for this is usually that:

- The applicant submits application documents to the provincial AMR, such as the:
  - application form;
  - manufacturing equipment layout and flow chart of the production process;
  - primary equipment and facility list;
  - safety-related standard operating procedure (SOP);
  - quality management SOP; and
  - any other documents required by the provincial AMR.
- The provincial AMR reviews the application documents, conducts on-site inspections when necessary, and determines whether to grant the manufacturing licence.

Marketing

The distribution of health foods and FSMP requires an appropriate food distribution licence. The application procedure involved the following:

- The applicant submits application documents to the competent local AMR at or above the county level, usually including the:
  - application form;
  - equipment and facility layout and operation processes;
  - food safety-related SOP; and
  - any other documents required by the competent local AMR.
- The competent local AMR reviews the application documents, conduct on-site inspections when necessary, and determines whether to grant the food distribution licence.

However, specific full nutritional formula foods (special FSMP) can only be distributed to consumers through medical institutions or drug retailers (and so no food distribution licence is needed).

Distribution of health foods/FSMP on the internet (except special FSMP) is legally permissible. The distributor must obtain the normal food distribution licence.

25. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

Generally, health foods and FSMP licensed or approved in another jurisdiction must be registered or filed before importation into China. For imports, in addition to the usual application materials (*see Question 24*), the applicant must also submit:

- An overseas manufacturer qualification certificate.
- A certificate proving sales for more than one year, or a safety report.
- The relevant technical laws, regulations, and standards enforced in the country (or region) of origin.
- The package, label and instructions of the product marketed in the country (or region) of origin.
- Any other materials required by the SAMR.

However, certain health foods licensed or approved in another jurisdiction can be distributed in China without registration/filing, if they are sold directly to consumers in China through cross-border e-commerce (CBEC) in compliance with the following requirements:

- They are imported through the "online purchase bonded imports mode" or the "direct purchase import mode."
- They are health foods included in the List of Goods under Cross-border E-commerce Retail Importation (2019) (issued by the Ministry of Finance and other relevant ministries), and are for personal use only.
- The tariff applicable to CBEC retail imports is paid.
- They are sold through an e-commerce platform linked with the customs network, or through other platforms where relevant enterprises transmit transaction and payment information to Customs.
- The overseas distributor entrusts a domestic enterprise to complete customs formalities and other regulatory requirements.

26. Is it possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically?

Imports

Importers of health foods/FSMP must:

- Generally, complete registration requirements and provide labels and instructions in Chinese, unless the type of import is exempted from registration requirement by law (*see Question 25*).
- Register as a foreign trade operator with the local commerce bureau.
- Allow customs authorities to review the imported food and documents, and pay the required customs tariffs.

Failure to meet these requirements may lead to certain administrative penalties, including warning, confiscation, suspension, fines or licence revocation. Serious breaches may trigger criminal liability.

Exports

It is legally permissible to export health foods and FSMP outside China. There are no particular administrative requirements.

27. What are the general requirements to advertise natural health products?

As well as the general regulatory requirements and restrictions applicable to all types of advertisements (*see Question 8*), the main additional requirements for an advertisement of health foods/FSMP are that it must:

- Ensure its content align with the product registration certificate/filing certificate, label, and instructions.
- Not contain:
  - assertions or guarantees about the product's efficacy or safety, or its prevention or treatment of illness;
  - assertions or implications that the product is necessary for health protection;
  - comparisons with drugs and other health foods; or
  - recommendations or endorsements from an advertising spokesperson.
- Not be disguised in the form of informational health or well-being knowledge.
- Not be published on mass media targeted at minors.
- Not advertise special FSMP in the mass media or public places, but only in the professional pharmaceutical or medical journals designated by the NHC and NMPA.

DATA

28. What data and information laws must be complied with by life sciences businesses that collect, use or otherwise deal in patient data (including through health apps)?

Chinese law does not define "patient data." Regulatory requirements on data generated from a patient's medical treatment are contained in various rules and regulations. For example:

- **Personal information.** The *Civil Code* (with effect from 2021 and the *Cyber Security Law* (with effect from 2017) define personal information as all kinds of information, recorded by electronic means or otherwise, used to independently identify or be combined with other information to identify specific natural persons (including, for example, natural persons' names, ID numbers, and biometric information). Data subjects must consent to the collection, use, storage, sharing, transfer and other processing of personal information. Cross-border transfer of personal information may trigger requirements of advance self-assessment or government-driven assessment of the data protection standards of the recipient jurisdiction.
- **Medical records.** The *Regulations on Management of Medical Records in Medical Institutions* define medical records as the sum of texts, symbols, graphics, images and slides produced in medical activities by medical personnel, including outpatient, emergency and hospitalisation medical records. Medical records are kept in medical institutions and can only be accessed by staff providing medical services, staff and institutions for medical record management, and other medical staff and institutions for scientific research and teaching purposes.

- **Population health information (PHI).** The *Administrative Measures on PHI (For Trial Implementation)* define PHI as the basic population information, medical and health service information and other population health information generated in the process of service and administration by medical institutions at all levels according to relevant laws and regulations. PHI must be stored in a server in China, and cross-border transfer of PHI may trigger an advance data safety assessment requirement.
- **Health care big data (HBD).** The Administrative Measures for Standards, Security and Services of National Big Data on Health and Medical Treatment (for Trial Implementation) define HBD as data relating to health care generated in the course of disease prevention and control as well as health management. Cross-border transfer of HBD may trigger an advance self-assessment or government-driven assessment requirement.
- **HGR information.** The *HGR Regulation* defines HGR information as data generated from the use of human genetic resource materials (*see Question 10*). Collection, storage, use and sharing of HGR information with foreign entities may be subject to advance regulatory approval or filing with the HGR administrative office.

In recent years, various laws and regulations, and also recommended national/industrial standards, have been published to regulate data handling activities and to facilitate the compliance with data handling. It is therefore advisable to monitor the data protection regulatory developments closely.

29. What restrictions and regulatory requirements apply to the testing of life sciences products on human and animal subjects?

Experiments on Animals

Before conducting clinical trials of life sciences products on human, experiments on an animal are typically required. These experiments must generally:

- Be conducted by a qualified institution that has a good laboratory practice certificate.
- Be conducted on qualified experimental animals.
- Have in place an experiment research plan, quality management process, and other relevant SOPs.
- Comply with the *Good Laboratory Practices for Non-Clinical Drug Research* (with effect from 2017)

Depending on the particular experiment, other requirements may apply.

Clinical Trials on Humans

When conducting clinical trials on humans, the following requirements generally apply:

- Conduct the trial in a qualifying institution (normally, a qualifying medical institution recognised by the health bureau).
- Obtain signed informed consent from trial subjects.
- Obtain approval from ethics committees, before the start of the trial and any material changes during the course of the trial (for example, of the protocol).
- Obtain advance regulatory approvals from, or make the correct filings with, the competent authorities.
- Ensure the investigational drug comply with the requirements of good manufacturing practice (GMP) applicable to drugs for clinical trial.
- Establish an effective trial protocol, quality management process, and other work process SOP.
- Comply with *Good Practice for Clinical Trials of Drugs* (revised in 2020).

Depending on the particular clinical trial, other requirements may apply.

REFORM

30. Are there any plans to reform the rules on the development, manufacture, marketing and advertising of life sciences products and services?

In recent years, a series of laws and regulations have been published or revised (or proposed to be published or revised) to encourage R&D of life science products and services:

- **Drugs.** The revised DAL expressly sets out certain preferential treatments to encourage drug development, such as the MAH system, fast-track registration policy, breakthrough therapies, and priority review (*see Question 6*). There have also been recent revisions of several implementing rules regulating the registration, manufacturing and distribution of drugs, as well as the Good Clinical Practice (GCP) rules. Several draft consultations have been issued by the relevant authorities for public comment with the aim of balancing industrial innovation and drug safety (including consultations on patent protection for drugs, vaccine MAH system, online sales of prescription drugs, and investigator-initiated clinical trials).
- **Medical devices.** The revised RSAMD came into effect on 1 June 2021. It encourages the development of innovative medical devices through mechanisms such as priority review, and also strengthens product quality supervision and MAHs' responsibilities. The *Administrative Measures on the Registration and Record-filing of Medical Devices* came into effect on 1 October 2021. In addition, two draft revision rules relating to the manufacture and distribution of medical devices have been published for consolidation. They mirror the principles set out in the RSAMD and provide detail on implementing requirements. There is no time scale for when the final rules will be enacted.
- **Health foods and FSMP.** A series of rules have been issued to guarantee food safety. For health foods, after the *Administrative Measures for the Registration and Filing of Health Foods 2020* came into effect on 23 October 2020, the SAMR issued (sometimes in conjunction with other authorities) various draft regulations for public consultation regarding raw material catalogues, catalogues of permitted health functions to be claimed, and dosage and technical requirements of health foods. For FSMP, the National Institute of Hospital Administration of the NHC issued the *Expert Consensus on Clinical Management of FSMP (Draft for Public Comments)* on 29 January 2021 to strengthen the standardised application of FSMP in clinical practice.

Under the 14th Five-Year Plan (2021-2025) for National Economic and Social Development and the Long-Range Objectives Through the Year 2035, the Chinese Government expects to take more action, including:

- Reforming the disease prevention and control system.
- Improving the prevention system of public health incidents.
- Encouraging the development of high-end medical equipment.

These aims are likely to be followed in the future by laws and regulations aimed at facilitating progress in these areas.

Practical Law **Contributor Profiles**

Alan Zhou, Partner

Global Law Office

T +86 21 2310 8200
F +86 21 2310 8299
E alanzhou@glo.com.cn
W www.glo.com.cn

Areas of practice. General corporate; compliance and risk control.

Non-professional qualifications. LLB, Shanghai International Studies University; Executive MBA, China Europe International Business School

Recent transactions

- Routinely represents multinational corporations, such as Sanofi, Siemens, AstraZeneca, GSK, Boehringer Ingelheim and Novartis, as well as local life sciences and health care companies.
- As a participant or external counsel, has been engaged by local authorities and industrial associations to advise on legislation and industrial standard in the life and health industry, with topics including online hospital, digital marketing, medial insurance reform, medical representative management, and other compliance topics.

Languages. Chinese, English

Professional associations/memberships. Chief supervisor and chairman of the committee of industry experts Chip Association; Vice director, Association of Compliance Professionals (ACCP); Executive manager, secretary general of the medical association committee, China Europe International Business School Healthcare Industry Association; Vice chairman of the management committee, China Pharmaceutical Industry Association.

Publications

- *Global Practice Guide Life Sciences China Law & Practice, Chambers.*
- *Pharmaceutical Advertising: China Law & Practice; Anti-corruption China Law & Practice, Chambers.*
- *The International Investigation Review, Legal Business Research (Ninth, Tenth & Eleventh Edition).*
- *Bribery & Corruption Annual Review, Legal 500.*

Charlene Huang, Partner

Global Law Office

T +86 21 2310 8201
F +86 21 2310 8299
E xuchunhuang@glo.com.cn
W www.glo.com.cn

Professional qualifications. PRC licensed lawyer

Areas of practice. M&A; general corporate; health care industries.

Non-professional qualifications. LLM, East China University of Political Science and Law; LLM, Cardiff University

Recent transactions

- Greenfield foreign investment in the form of JV or WFOE.
- Acquisitions of equity interests in Chinese state-owned or private companies.
- Restructure or integration of China businesses of multinational group companies.
- Strategic co-operation and contractual controlling model.
- Daily advice and substantial projects for clients including Abbott, Align Tech, Boehringer Ingelheim, Eli Lilly, GE and HRC.

Languages. Chinese, English

Publications

- *Pharmaceutical Advertising: China Law & Practice, Chambers Global Practice Guide.*
- *Note on Cybersecurity and Data Protection in Healthcare, Thomson Reuters.*
- *Impact of Two Invoicing system, speech in seminars of ACCP, Everlaw, Intelligeast, and others.*
- Advice on legislation updates in healthcare industries for *Bloomberg BNA*, topics including GCP, medical device registration, vaccine distribution, and medical representatives.

Samantha He, Of Counsel

Global Law Office

T +86 10 6854 6516
F +86 10 6584 6666
E samanthahe@glo.com.cn
W www.glo.com.cn

Professional qualifications. PRC licensed lawyer

Areas of practice. M&A; compliance and risk control.

Non-professional qualifications. LLM, Erasmus University Rotterdam; LLM, East China University of Political Science and Law; LLB, East China University of Political Science and Law

Recent transactions

- Advising clients on NMPA regulatory matters across a range of sectors, including drugs and biologics, medical devices, and e-health products and services.
- Counselling clients on regulatory and compliance matters, including advertising, anti-corruption and bribery, medical affairs, manufacturing and distribution.

Languages. Chinese, English

Publications. *Life Sciences China Law & Practice, Chambers Global Practice Guide.*