The Life Sciences Law Review

Third Edition

Editor
Richard Kingham

Law Business Research

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For further information please email
Nick.Barette@lbresearch.com

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EDITOR'S PREFACE

The third edition of *The Life Sciences Law Review* extends coverage to a total of 36 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. As before, the chapters are arranged to describe requirements throughout the life cycle of a regulated product – from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Each of the chapters has been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this annual publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2015

Chapter 7

CHINA

Shaoyu Chen and John Balzano[1]

I INTRODUCTION

China's drug and device legislation has developed rapidly from simple laws and regulations enacted gradually up to 2000, to a substantial body of regulation covering the major areas of pre-market approval and post-marketing surveillance today. Even greater reform is now on the horizon in many spaces, and China is becoming involved in debates at the international level regarding accepted best practices. A growing body of health-care regulation, including medical ethics, pricing and reimbursement, and standards for clinical research, is also emerging to influence the drug and device industries.

The legislative reform has been accompanied by government reform. In 2013, China reorganised its State Food and Drug Administration into a more powerful ministry-level agency, referred to as the China Food and Drug Administration (CFDA). The reforms to the CFDA are part of an effort in China to upgrade the capacity of the agency to handle increasingly complex scientific and technical issues. Both the CFDA and local provincial level food and drug administrations (PFDAs) have continued to recruit personnel with relevant expertise and develop the infrastructure to conduct sophisticated assessments of the safety and effectiveness data related to products and ingredients. This chapter is intended to share the changing shape of the basic framework of this legal regime and the agencies that implement it, as well as the directions for reform in the future.

China's drug regulatory regime has arguably developed faster than other spaces, paving the way for the reforms that have come into effect with, for example, devices. The primary statute regulating medicines in China is the Drug Administration Law (DAL), which was enacted by China's national legislative body, the National People's

1 Shaoyu Chen is a partner and John Balzano is a special counsel at Covington & Burling, LLP.

Congress, in 1984 and then subsequently amended in 2001.[2] Several regulations have been promulgated under the DAL to govern various activities, such as development, registration, manufacturing and marketing of drugs. China will soon significantly revise the DAL; a revision has been in the works for several years now. This revision could bring important change in many areas, as will the implementing regulations that the CFDA issues after its enactment.

China has not enacted a law covering medical devices, but it has enacted a framework regulation, the Regulations for the Supervision and Administration of Medical Devices (RSAMD), and a number of implementing regulations covering registration, production and distribution, similar to those that exist for drugs.[3] In 2014, China completely revised the RSAMD, and the CFDA issued an entirely new set of substantially revised implementing regulations, as well as new regulations and guidance documents in some previously unregulated areas, such as device distribution and device clinical trials.

The CFDA is the primary pharmaceutical and medical devices regulatory agency in China. It enjoys power over most aspects of pre-market approval and a substantial part of post-marketing activities. Under the current arrangement, the CFDA is organised into departments and affiliated centres. The departments have responsibility for administration and enforcement functions, while the affiliated centres are responsible for scientific review and for recommending decisions for the departments to adopt and implement.

For drugs, the primary departments and centres include the Department for Drug and Cosmetic Registration and the Department for Drug and Cosmetic Safety Supervision. The affiliated centres are the Centre for Drug Evaluation (CDE) and the Centre for Drug Re-evaluation (CDR). The CDE evaluates clinical trial and marketing authorisation applications. The CDR includes the National Centre for Drug Adverse Event Monitoring, which is also responsible for device adverse event monitoring.

The CFDA similarly has registration and supervision departments for medical devices. The registration department is subdivided by whether the devices use electrical power or not, as well as including a department for supervising research and development. The supervision department is divided into divisions responsible for regulating manufacturing, distribution, and monitoring and evaluation. The Centre for Medical Device Evaluation (CMDE) is the affiliated centre responsible for organising the technical evaluation of medical devices.

2 Drug Administration Law (amended February 2001), http://eng.sfda.gov.cn/WS03/CL0766/61638.html.

3 Regulations for the Supervision and Administration of Medical Devices (RSAMD), www.cfda.gov.cn/WS01/CL0784/97814.html. These regulations cover *in vitro* diagnostic reagents (IVDs), but IVDs are regulated separately under a specialised set of implementing regulations. Throughout this article when we refer to medical devices we are referring to non-IVD devices, unless otherwise indicated.

With an official headcount of 345 at the national level, the CFDA relies on PFDAs and similar food and drug regulatory authorities in the municipalities[4] to carry out various activities, including accepting applications, conducting on-site checks and inspections, collecting samples, and issuing manufacturing and distribution licences. These provincial agencies receive their budget and their personnel allocation from the provincial governments, and therefore they can vary in terms of capacity. State accredited laboratories and clinical trial sites (i.e., in state-owned hospitals) also play a role in drug and device regulation in China.

Although the CFDA is the primary agency for pre-approval, other government agencies also play important roles in the pharmaceutical regulatory framework. For example, the National Development and Reform Commission (NDRC) plays a key role in articulating drug and device pricing policy. The State Administration for Industry and Commerce (SAIC) plays a significant role in enforcing advertising and promotion and other consumer protection laws. The National Health and Family Planning Commission (NHFPC) (formerly the Ministry of Health) oversees all aspects of the medical profession and hospitals (which include CFDA-accredited clinical trial sites for drugs and devices), and it plays a role in determining the essential drugs that may be reimbursed under China's state insurance plans. The Ministry of Personnel and Human Resources also plays a role in setting the formularies for these insurance plans. For imported drugs, two additional government agencies, the Chinese Customs and the Administration of Quality Supervision, Inspection and Quarantine, are involved in product-quality inspections and customs clearance. This sharing of responsibility creates a complex system in many respects.

II THE REGULATORY REGIME

i Classification

Drugs

The DAL defines 'drugs' broadly as:

> *articles which are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications, usage and dosage are established, including Chinese crude drugs, prepared tranches of Chinese crude drugs, traditional Chinese medicine preparations, chemical drugs substances and their preparations, antibiotics, biochemical drugs, radioactive pharmaceuticals, serum, vaccines, blood products and diagnostic agents.*[5]

The CFDA has enormous discretion to determine whether a substance constitutes a drug or fits into another regulatory regime. As we will discuss below, the CFDA does recognise

4 While varying from year to year, the local food and drug agencies and affiliated organisations at PFDAs and municipalities have a total approximate headcount of 80,000 (direct and affiliated).

5 Article 102 of the DAL.

some category overlap. When products may be considered drug/device combination products, the CFDA and a combination of experts from either the CDE, CMDE or both will make a decision as to whether to regulate the product as either a drug or a device.

Once determined to be a drug, the regulatory requirements applicable to a product will be determined by its pathway and its features. The primary pathways are either a domestically manufactured drug or an imported drug.

Before a company can market a drug in China, the DAL requires that the company submit and obtain government approval of a drug registration application, which may be divided into two parts: (1) a clinical trial application and (2) a subsequent application for approval to market the drug.[6] If the drug is to be manufactured in China, the company must also submit a manufacturing licence application and obtain good manufacturing practice (GMP) certification of its facilities.[7] If the drug is to be manufactured abroad, the company must apply for an import drug licence (IDL).[8] In either event, approval requires a robust demonstration of safety and efficacy, showing that the drug's benefits outweigh its risks. After approval, a drug manufacturer is required to conduct pharmacovigilance, including having systems in place to report and evaluate adverse event data and conduct any necessary recalls, meet GMP standards, and comply with advertising and promotional requirements. Some of these requirements will also differ based on whether the drug is an imported drug or a domestically manufactured drug.

The DAL and Provisions for Drug Registration (PDR)[9] classify a drug either as a domestic drug or as an imported drug, depending on whether the finished dosage form of the drug is manufactured inside or outside China. The PDR then classifies domestic drugs into three types: traditional Chinese medicines and natural drugs, chemical drugs and biological drugs. Within each classification, drugs are then placed into categories and subcategories. These classifications and sub-classifications determine the clinical data and other requirements necessary for registration. Specifically, chemical drugs are classified into six categories.[10] Categories 1 and 3 are further classified into six and four subcategories, respectively. Biologics are first classified as either therapeutic or preventive, then further classified into 15 subcategories under each heading.[11] Classification depends on the drug's marketing approval status in China and abroad, source material, composition, and other factors. The subcategories are not mutually exclusive, which can lead to confusion and duplicative requirements.

As we explain below, certain types of drugs may be subject to separate and heightened requirements and require additional special permissions. An example of this would be drugs that the CFDA classifies as 'narcotic drugs' and 'psychotropic drugs', which require a special manufacturing licence to implement state manufacturing quotas.

6 Article 29 of the DAL.

7 Article 8 of the DAL.

8 Article 39 of the DAL.

9 The Provisions for Drug Registration (2007), http://eng.sfda.gov.cn/WS03/CL0768/61645.html.

10 Appendix 2 of the PDR.

11 Appendix 3 of the PDR.

Devices

The RSAMD define 'medical devices' broadly as:

> *Medical devices means the instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or related articles directly or indirectly used with human bodies, including the computing software required. Their effectiveness is primarily achieved by physical or other similar means and not by pharmacological, immunological or metabolic means, although it may be assisted in its function by such means, the purpose of which is to achieve the following objectives:*
>
> *(1) diagnosis, prevention, monitoring, treatment or mitigation of diseases;*
>
> *(2) diagnosis, monitoring, treatment or mitigation of injuries or the functional compensation thereof;*
>
> *(3) inspection, replacement, adjustment or support of the physical structures or physiological processes;*
>
> *(4) life support or sustaining;*
>
> *(5) pregnancy control; and*
>
> *(6) provision of information for medical or diagnostic purposes by inspecting the samples of human bodies.*[12]

The RSAMD classify medical devices into three classes:

> *Class I medical devices means medical devices with low risks, and those for which safety and effectiveness can be ensured through routine administration; Class II medical devices means medical devices with moderate risks, which must be strictly controlled and administered to ensure their safety and effectiveness; Class III medical devices means medical devices with relatively high risks, which must be strictly controlled and administered through special measures to ensure their safety and effectiveness.*[13]

As with drugs, the CFDA and its relevant divisions have significant discretion to determine what constitutes a medical device and what class it fits into. Applicants for a device registration may make their own determination as to classification and then submit their application to the CFDA or they can treat their device as a Class III and ask the CFDA to make adjustments.[14] The CFDA oversees an electronic portal that permits applications for a predetermination of device classification.

The CFDA maintains and periodically updates a classification catalogue showing its medical device classification decisions. By reference to this catalogue, along with general classification rules, the applicant can make its own determination as to classification. In 2013–2014, the CFDA proposed to break up the general catalogue into more specific catalogues. For example, it issued a proposed catalogue devoted to device software. These

12 Article 76 of the RSAMD. This is an edited version of the translation that appears on www.ChinaLawInfo.com.

13 Article 76 of the RSAMD.

14 Article 16 of the RSAMD.

changes have not yet been finalised. Because classification determines data requirements for registration, it is often important to determine the class before starting trials or filing for an exemption.

As with drugs, the RSAMD and the implementation Measures on Medical Device Registration classify a medical device either as a domestic device or as an imported device, depending on whether the finished device is manufactured inside or outside China. If it is an imported device, the CFDA reviews and approves a registration application for Class II and Class III devices. Class I imported devices go through a notification system, which the CFDA also administers. For domestic devices, the review and the reviewing authority depend on the classification. Class I device manufacturers must notify municipal authorities before marketing their products. A provincial level FDA approves Class II medical device registration applications; and the CFDA reviews and approves Class III medical device registration applications.[15] The Measures on the Registration of In Vitro Diagnostic Reagents, which were also amended in 2014, set out a similar classification and registration scheme for IVDs.

Combination products

The CFDA issued a notice in 2009 to govern its review of drug and device combination products.[16] If the primary mode of action of a product is medicinal, the CDE will review it as a drug, or lead a joint and parallel review by both the CDE and the CMDE. If the primary mode of action of a product is not medicinal, the CMDE will review it as a device, or lead a joint and parallel review by CMDE and CDE. The CFDA will not approve a combination product that is imported into China, if the product as a whole has not received any approval from the exporting country, or if the drug component of the product has not been approved in China or in the exporting country.

ii Non-clinical studies

Non-clinical studies for drugs must comply with the CFDA Drug Good Laboratory Practice Regulations,[17] which for the most part follow similar good laboratory practice (GLP) requirements in other countries. Non-clinical studies for drugs must be conducted by institutions that have been certified by the CFDA to perform such studies to be accepted as part of a drug registration application. The CFDA has not issued specific GLP regulations for medical devices.

iii Clinical trials

Drugs

Before a clinical trial can be initiated in China, the sponsor must submit a clinical trial application (CTA) to the CFDA, and the CFDA must approve it and issue a clinical trial permit. The CFDA's review of a CTA takes on average about one year or more; an expedited review is available for drugs that are intended to treat certain

15 Article 5 of the Measures on Medical Device Registration.

16 Notice Concerning Registration of Drug and Device Combination Products (2009).

17 Good Laboratory Practice Regulations (2003), www.sfda.gov.cn/WS01/CL0053/24472.html.

serious or life-threatening illnesses. The CFDA requires that investigational drugs be manufactured at GMP facilities and comply with GMP standards. It also requires that government-certified laboratories conduct quality testing to confirm conformity with the quality standards.[18] The sponsor must also seek review and approval of the clinical trial by a qualified ethics committee, and by a clinical trial management committee for each clinical trial site; a process that can take more than a few weeks.

Clinical trials can be conducted only at institutions that have been inspected and certified by the CFDA for that type of clinical investigation. Clinical trials in China are also governed by pharmaceutical good clinical practice (GCP) regulations,[19] which largely follow similar GCP regulations in other countries. The GCP regulations and the PDR set out sponsor and investigator obligations, including for serious adverse events. The CFDA, or ethics committee, can hold or terminate a study for safety reasons.

Once a clinical trial protocol is approved, however, it is very difficult to amend, even for small changes. The CFDA's regulations do not include a procedure for amendments. This shortcoming has led to applicants having to file an entirely new CTA when making changes to their approved CTA. Proposed amendments to the PDR would remedy this problem to some extent by permitting amendments to certain items of approved CTAs for trials that have not yet entered Phase III.

For investigational arms of clinical trials, the CFDA Provisions for Drug Registration specify the following minimum numbers of study subjects, and the trial must have sufficient statistical power.[20]

	Phase I	*Phase II*	*Phase III*	*Phase IV*
Chemical drug	20–30	100	300	2000
Therapeutic biologic	20	100	300	Not specified
Preventive vaccine	20	300	500	Not specified

Devices

Clinical data are used to establish safety and efficacy of medical devices to be registered for marketing in China.[21] In general, manufacturers must submit clinical trial data to register Class II and Class III medical devices.[22] No clinical trial is required for Class I devices.[23]

In 2014, the revised RSAMD broadened the exemptions from clinical trials for certain devices and for IVDs. The exemptions for devices include (1) devices for which there is an identical type of device on the market with a well-established safety record following many years of clinical use; (2) devices that can be evaluated effectively through

18 Articles 35 and 36 of the PDR. Also see the CFDA clinical trial flow chart: http://eng.sfda.gov.cn/WS03/CL0769/61658.html.

19 Pharmaceutical Good Clinical Practice Regulations (2003), www.sfda.gov.cn/WS01/CL0053/24473.html.

20 Appendixes 2-3 of the PDR.

21 Article 17 of the RSAMD.

22 Article 17 of the RSAMD.

23 Article 17 of the RSAMD.

non-clinical data; and (3) devices that can be evaluated through pre-existing data on the same types of devices.[24] To further define these categories, the CFDA is issuing catalogues of exempt devices, and it has proposed guidance on how to determine whether a device falls under one of these broad exemptions. Exemptions similar to (1) and (2) also exist under the revised IVD regulations.[25] In 2014, the CFDA issued catalogues of Class II and III medical devices that are exempt from the clinical trial requirement according to the criteria set forth in the revised RSAMD.[26]

Clinical trials of Class II and most Class III medical devices do not require CFDA approval. However, the CFDA has issued a catalogue of high-risk Class III devices for which pre-approval of the clinical trial is required.

All trials for both medical devices and IVDs must take place at hospitals and other health-care institutions that the CFDA has accredited to conduct device trials.[27] The system of accreditation is still developing. The CFDA issued proposed regulations on the accreditation of device clinical trial institutions in December of 2014.[28] In addition, under the revised RSAMD, device trials must comply with medical device GCP; the CFDA is still in the process of developing these. All medical device clinical trials must be notified to the provincial-level government where the clinical trial sponsor is located.[29]

iv Named-patient and compassionate use procedures

China has not promulgated regulations or formally established any mechanism to allow named-patient or compassionate use of a drug or medical device outside clinical trials and prior to marketing authorisation. The CFDA permits limited drug compounding or medical device manufacture by hospitals for use on their own patients, sometimes without having to receive CFDA clinical trial approval or marketing authorisation.[30]

v Pre-market clearance

Drugs

CFDA review and approval is required for the domestic production or importation of drugs. The Provisions of Drug Registration (PDR) provide five types of drug registration application: (1) new drug applications, (2) generic drug applications, (3) imported drug

24 Id.

25 Articles 18–20 of the Measures on the Registration of In Vitro Diagnostic Reagents (2014).

26 Notice on Issuing the Catalogue of Class II Medical Devices that are Exempted from Conducting Clinical Trials (2014), available at www.cfda.gov.cn/WS01/CL0087/105224.html; Notice on Issuing the Catalogue of Class III Medical Devices that are Exempted from Conducting Clinical Trials (2014), available at www.cfda.gov.cn/WS01/CL0087/105225.html.

27 Article 18 of the RSAMD.

28 Measures for the Accreditation of Medical Device Clinical Trial Institutions (draft for public comment), available at www.cfda.gov.cn/WS01/CL0779/110987.html,

29 Article 18 of the RSAMD.

30 Article 25 of the DAL; Article 10 of the Regulations for the Supervision and Administration of Medical Devices.

applications, (4) supplemental applications, and (5) re-registration applications.[31] With the exception of (4) and (5), the type of application depends on where the finished dosage form of the drug is manufactured. If manufactured outside China, the drug is considered an imported drug, and an imported drug application must be submitted to obtain an imported drug licence. If the drug is manufactured inside China, the drug is considered a domestic drug, and either a new drug application or a generic drug application must be submitted to obtain the drug manufacturing licence.

Imported drug application

In general, the drug must have been approved for marketing in the country where the manufacturer is located. If not yet approved, the CFDA is given the discretion to approve it, if the application provides adequate data to establish safety and efficacy, and there is clinical need in China. The manufacturer submits an imported drug application, and submits drug samples from three batches to be tested by the National Institute of Food and Drug Control (NIFDC) for conformity with product specifications and quality standards. The manufacturer must also appoint a local entity in China to act as the agent for the imported drug registration.[32] The CDE reviews the application data for safety and efficacy. If safety and efficacy are established, and the NIFDC drug sample testing results are satisfactory, the CFDA will approve the application and issue an imported drug licence.

New drug application

This is required if the drug is manufactured in China, but the drug has not been marketed in China. The PDR require that a new drug application be used for chemical drugs classified in categories 1 to 5, and for all categories of therapeutic biologics and vaccines, including biosimilars. The new drug application can be submitted by the manufacturer or the research institute that develops the drug.

For a new drug application, the CDE assesses safety and efficacy. If established, it will order a pre-approval GMP inspection, during which drug samples will also be taken during live production, and sent for testing by the NIFDC to check conformity with product specifications and quality standards. If the pre-approval GMP inspection and NIFDC testing are satisfactory, the CFDA will approve the application and issue a drug approval number, provided the manufacturer has already obtained a drug manufacturing facility permit.

Generic drug application

This is required if the drug is manufactured in China, and the application is for a drug that has the same active ingredient, route of administration, dosage form, strength, and therapeutic effect as one that 'the CFDA has approved and covered under national

31 Article 11 of the Provisions for Drug Registration (2007).

32 Articles 84-95 of the PDR.

standards'.[33] A generic drug application usually does not include data from full clinical studies. The CDE review of a generic drug application proceeds in parallel with manufacturing site inspection and collection of drug samples by the provincial FDA, as well as drug quality testing by the NIFDC. If results are satisfactory, the CFDA will approve the application and issue a drug approval number to the manufacturer, which should have already obtained a drug manufacturing facility permit.[34]

The pathway for biosimilars is somewhat different. That is to say, biologics for which there is an existing standard may be brought on the market. However, the PDR require that all biologics go through the application pathway for new drugs, and do not provide for a separate generic biologic category.[35] But the application requirements may still be different depending on the subcategory of biologics. For example, biologics for which there is a pre-existing national standard typically only need to conduct Phase III studies in China.[36] In 2014, the CDE released draft guidance on biosimilars, intended to strengthen the methods for research and development of candidates and their comparison to reference originator products, as well as some provisions on labelling and pharmacovigilance.[37] The way that this guidance will interact with existing law and regulation is not yet entirely clear.

Approval timelines

The total time for review, site inspection, drug sample testing, and final approval of an imported drug licence, a new drug application or a generic drug application can take one to two years. Most of this time is occupied by the CDE review process. The PDR provide for 150 business days for CDE review of new or imported drug applications, and 160 business days for CDE review of generic drug applications. In practice, CDE review often takes longer. If the CDE needs additional information, it can issue a request to the applicant, and the review clock stops. The applicant will have four months to provide the additional information, and the CDE will have an additional 40 days to review the additional information. Requests for additional information are common in

33 Under the appendices to the PDR covering small molecule and biological products, these are referred to as applications for drugs (or biologics) for which there is an existing drug standard (i.e., category 6 for drugs and category 15 for biologics). 'National Drug Standards' refers to all manner of drug standards, including drug registration standards, the PRC pharmacopoeia, and other drug standards issued by the CFDA, covering technical requirements including quality parameters, inspection methods and production processes. 'Drug registration standards' means the drug standards approved by the CFDA for a specific applicant, which is the basis for drug production and the monitoring and administration of the drugs. Drug registration standards must not decrease the standards set forth in the current pharmacopoeia. See Article 136 of the PDR.

34 Chapter 5 of the PDR.

35 Article 12 of the PDR.

36 Appendix 3 of the PDR.

37 Draft Guidance on the Research and Development and Technical Evaluation of Similar Biotherapeutic Products, available at www.cde.org.cn/zdyz.do?method=largePage&id=212.

all applications, and also sometimes repeated, although the CDE is required to avoid repeated requests. Reviewers may meet with the applicant upon request but are not required to do so.

Fast-track review is available for certain drugs that treat serious or life-threatening conditions, including new drugs for treatment of HIV, cancer or orphan diseases, and new drugs that treat diseases for which no effective therapy is available. Publicly available information suggests that the fast-track mechanism has in fact shortened review times. For example, in 2008 the CDE reviewed four imported drug applications for anti-HIV drugs in an average of nine and a half months.

Re-registration application

The registration for an imported or domestic drug is valid for five years. Six months prior to expiry of the registration, the applicant must submit a re-registration application to the CFDA if an imported drug, or to the PFDA if a domestic drug. Re-registration applications generally do not require new clinical data, though data from required Phase IV studies must be provided, and the CFDA may deny an application for re-registration if specified Phase IV commitments have not been met. The CFDA or PFDA must complete the review and make an approval or denial decision within six months of accepting the filing. If the re-registration application is not approved, drugs manufactured after expiry of the existing marketing or manufacturing authorisation may not be marketed in China.[38]

Supplemental drug application

Certain post-approval changes to a drug, whether imported or domestic, require CFDA approval of a supplemental drug application. The applicant must be the company that holds the existing marketing or manufacturing authorisation. While major post-approval changes require the CFDA or PFDA review and approval, some minor changes can be notified to the agency and implemented without review and approval.[39]

Devices

Some form of pre-market review and approval is required for domestic production or importation of all three classes of medical devices. Domestic and imported Class I devices must be notified to either the municipal food and drug regulatory authority where the manufacturer is located or the CFDA if manufactured abroad, before being placed on the market.

As noted above, domestically manufactured Class II devices must be reviewed and approved by a PFDA. Class III medical devices, as well as Class II and III imported medical devices, must be approved at CFDA level. For imported devices, the applicant must appoint a regulatory agent in China. There is no longer a requirement that the applicant appoint an after-sales agent. Government-certified laboratories first verify

38 Chapter 9 of the PDR.

39 Chapter 8 of the PDR.

conformity with the devices 'technical requirements', which the applicant must formulate in advance, and applicable standards through testing.

Biocompatibility data and clinical study data are often required for medical device approval. The CFDA is in the process of revising regulations and guidance related to the conducting of medical device trials in China pursuant to a mandate under the revised RSAMD.

The statutory time frame for agency decisions on the different types of devices depends on the class of the device and type of technical review required. For Class I devices, either the municipal FDA or the CFDA (if an imported device) will make an immediate determination of the completeness of materials and, if complete, accept the notification.[40] In the case of a Class II or III device, the relevant agency will make a determination as to whether the application is complete and appropriately filed (e.g., the agency has jurisdiction). Within three days of acceptance of the application, the materials are sent on to a technical review institution, which under normal circumstances has 60 days to complete its review. If outside expert help is required or the institution decides that it needs to conduct an inspection of the applicant's quality management systems, then the time may be extended beyond the 60 days. Similarly, the technical review institution may make a one-time request for any supplementary materials required. It then has another 60 days from the time of receipt of those materials to make its decision. Once the technical review is complete, the CFDA has 20 days to make a decision. In reality applicants may experience significant delays waiting for certain stages of this process to begin, and the process is typically longer than it appears in these timelines.[41]

After approval, a medical device registration certificate is issued by the appropriate level of FDA, and the certificate is valid for five years. Six months prior to the expiration of the five-year period, the manufacturer must submit a medical device re-registration application.

Changes to certain elements of the registration require amendments to the filings. The type of filing and its length depends on whether it is a 'licensing matter' or a 'registration matter'. Licensing matters include the product name, its model, its specifications, its structure, its composition, its scope of use (indications), its technical requirements and the foreign site of a manufacturer. Registration matters include the name of the applicant, the name of the agent, and their addresses. In the case of a domestic manufacturer, the address of the manufacturing site is also a registration item. For registration items, the original licensing agency will issue a revised licence in 10 working days. Licensing items require another technical review before a modified registration certificate will be issued.[42]

40 Notice on Several Matters Related to Class I Medical Device Notification (2014), available at www.cfda.gov.cn/WS01/CL0087/100816.html.

41 Articles 33-36 of the Measures on the Registration of Medical Devices.

42 Articles 49-53 of the Measures on the Registration of Medical Devices.

vi Regulatory incentives

Chinese regulation is designed in some respects to encourage innovation and development and manufacturing of products in China for which there is particular clinical need and value through expedited pre-market approval pathways. In contrast, post-approval regulatory incentives are very weak and their implementation incomplete. China has established a system of patent protection for drugs and devices. There is some limited data exclusivity for a new chemical entity, and market exclusivity implemented through a new-drug monitoring period for a new drug that is locally manufactured in China.

Drugs

Patent protection

China gives 20 years of patent protection. It does not give patent term extension to compensate for the CFDA drug registration review and approval time. An applicant is required to provide information on patent status in China as part of its drug registration application. If there are relevant third-party patents in force, the applicant must make a declaration of non-infringement, which the CFDA will publish.[43] In practice, however, the CFDA has not implemented these provisions rigorously, and there is no true patent linkage system in China. Non-infringement declarations do not automatically trigger the requirement that the applicant notify the patent owner, or cause an automatic stay on the CFDA decision. If the drug is covered by third-party patent rights and the applicant has not made a non-infringement declaration, the applicant can file the application two years prior to the patent expiration, and the CFDA can review the application and, if approvable, grant the approval upon expiry of the patent.[44]

Data protection

China offers six-year regulatory data-exclusivity protection to new chemical entities, as provided in Article 20 of the PDR and Article 35 of the Regulations for Implementation of the Drug Administration Law. Within six years of approval, the CFDA is not allowed to approve another application (usually a generic drug application) that includes or refers to the innovator's data unless the innovator has authorised such use, or the innovator data have been publicly disclosed. In practice, this provision is difficult to implement because the term 'new chemical entity' is not defined, and the CFDA has not issued procedures surrounding various aspects of this protection. As such, very few, if any, companies have experienced true benefit from this exclusivity. Innovator companies have continued to express concerns about the operation of the data protection provisions, including whether the CFDA approves generic drug applications prior to the expiration of the data protection period. The CFDA has promised to include a definition of a new chemical entity in the amendment to the DAL.

43 Article 17 of the Provisions on Drug Registration.

44 Articles 18–19 of the PDR.

Marketing exclusivity

China does not have true regulatory marketing exclusivity. Article 66 of the PDR provides that the CFDA has the discretion to set a 'new-drug monitoring period' of up to five years, when it approves the manufacturing of a domestic drug that is first in the class. The monitoring period is not available for imported drugs. During the monitoring period, the drug is under enhanced adverse event monitoring requirements, and the CFDA is not allowed to approve the clinical trial, manufacturing, or importation of another domestic or imported drug in the same class for the same indication. If, however, the approved domestic drug is not manufactured within two years of approval, the CFDA can approve another domestic or imported drug application. The monitoring period does not provide complete exclusivity, however, because if the CFDA has approved the CTAs of other applicants for the same drug, those applications may proceed to registration. If those other registration applications are approved, those drugs may also become part of the monitoring period.

Devices

The regulations for the registration of medical devices do not require patent certification or contain provisions on data or market exclusivity. The revised RSAMD expressly state that any patent disputes will be handled under the relevant laws (i.e., the Patent Law).[45] There are procedures for expedited review and approval of medical devices where there is a public health emergency and the same kind of device is not marketed in China, or is marketed but is in short supply. Medical devices undergoing expedited procedures also benefit from assistance from the CFDA during development and registration.[46]

The CFDA has also created an expedited pathway for review of applications for 'innovative devices'. To qualify as an innovative device, the patent for the technology must be held in China. The primary work on the product's design and use mechanisms must have been the first of its kind in China; its safety or functionality must be a fundamental improvement over comparable technology; it must be leading technology internationally; and the device must have clear clinical value. In addition, well controlled preliminary research must be completed, and there must be a basic product model. The data must be complete and traceable.[47]

vii Post-approval controls

Adverse events

Drug and medical device manufacturers are obligated to establish systems to report and analyse adverse reactions and product complaints, and meet any conditions imposed

45 Article 48 of the RSAMD.

46 Articles 4 to 5 of the Procedures for Emergency Review and Approval of Medical Devices (2009).

47 Article 2 of Procedures on the Examination of Innovative Medical Devices (Trial Implementation) (2014), available at www.sda.gov.cn/WS01/CL1237/96654.html,

as part of the product approval.[48] In 2011, the CFDA issued detailed regulations on adverse reaction reporting for drugs and devices. The Measures on the Administration of Adverse Drug Reaction Reporting and Monitoring (2011) require FDAs at national, provincial and municipal levels to set up adverse event collection systems, and imposes reporting and monitoring obligations on not only the drug manufacturer, but also drug distributors and health-care organisations. Specific reporting time frames and follow-up actions are set out for handling individual cases, clusters of cases, periodic accumulative reporting, enhanced monitoring and imported drug reporting.[49]

For medical devices, the CFDA promulgated the Measures on the Administration of Medical Device Adverse Event Monitoring and Re-evaluation (Interim), and issued Guidance on the Monitoring of Medical Device Adverse Event (Interim) to impose detailed adverse event reporting obligations on device manufacturers, distributors, and user facilities, as well as specific timelines and follow-up actions that are somewhat similar to those for drugs. This system has structurally remained largely the same under the revised RSAMD, but the CFDA released a phased-in plan in late 2013 for further developing a comprehensive network of medical device technical monitoring institutions at different local levels of government and implementing, in some cases, daily monitoring for high-risk devices.[50]

The CFDA has the authority to order mandatory recalls of drugs and medical devices because of serious adverse reactions or other safety issues.[51] Manufacturers and distributors also have different obligations, in varying circumstances, to cooperate with, report on or implement recalls.

Transfer of licences

Transfer of licences is more difficult to achieve in China than in, for example, the United States. Part of the reason is that CFDA regulations do not provide clear guidance on this issue and regulatory changes have created further uncertainty. Another reason is because of the connection between the product permission and the manufacturing facility permissions.

For domestically manufactured drugs the licences are issued to the specific manufacturer, for the specific manufacturing site, and for the manufacturing of the particular drug. In other words, the Chinese system is a combination of manufacturing authorisation and marketing authorisation. As a result, any transfer typically will trigger

48 See, e.g., Articles 41–44; 67–68; 121 of the PDR, and Article 169 for drugs; and Article 48 of the RSAMD (requires manufacturer to establish device AE reporting system, and tracking system on Class III devices).

49 The Measures on the Administration of Adverse Drug Reaction Reporting and Monitoring (2011), chapters 2 to 6.

50 Guiding Opinion on Further Establishing a System for Medical Device Adverse Event Monitoring, available at www.cfda.gov.cn/WS01/CL0845/93174.html.

51 The Measures on the Administration of Drug Recalls were promulgated in 2007, and the Measures on the Administration of Medical Device Recalls (Interim) were promulgated in 2011.

a review and approval process, where the qualifications of the transferee will be carefully examined. The supplement application will be denied if the transferee does not meet the relevant requirements, such as having qualified personnel necessary to comply with applicable GMP requirements. There are two licences involved: the drug manufacturing facility licence, which is issued to the manufacturing site and requires renewal every five years; and the drug manufacturing licence and the corresponding drug registration certificate and approval number, which require renewal every five years. The second licence can only be issued to an entity that has the first licence.

For drugs, transfer of licences in China would probably need to involve the transfer of the ownership of the manufacturing facility, and this is usually done via an equity acquisition of the holder of the two licences. In fact, the CFDA regulations have specifically prohibited any 'buying and sale, renting, or loaning of the licences', and any such activities could trigger revocation of the licences.

These issues with devices have been similar to those with drugs. Since the revision of the RSAMD, however, the situation with device licences is still developing, and therefore, it is not clear whether transfers of licences will remain equally complex. For Class II and Class III devices, the manufacturing facility licence is, as of the revision of the RSAMD, no longer a prerequisite for the product licence, but the product licences are required documents when applying for a manufacturing licence. As with drugs, the device licences may not be sold or rented out.[52]

But under the new system it is not clear whether the product is bundled to the site. Amendments to the applicant name may be easily accomplished for domestic devices. After 10 days, if the documents are complete, the relevant authority will issue the revised registration. Changes to the address of a domestic manufacturing site is a two-step process, in which the manufacturing licence is first amended and then the change to the product registration is notified to the authorities. Again, for the product registration notification, if the documents are complete, the authorities will issue a new registration within 10 days.[53] Therefore, amending the licence when acquisitions in China cause changes to the licensing information can and should be separate from a manufacturing licence and should be an easier process.

Class I device manufacturers only need to file details of their facilities for the record (and not to obtain a manufacturing licence) with local regulators and certify to compliance with relevant manufacturing requirements. These notifications are done in the name of the manufacturer. In the case of a change of ownership, under most circumstances, the new owner should be able to re-file relatively quickly. However, this system is still developing.

For imported drugs and medical devices, the Chinese system is more akin to a marketing authorisation system, where the only licence is an imported drug or device

52 Article 64 of the RSAMD.

53 Articles 49–50 of the Measures on Medical Device Registration; Article 15 of the Measures for the Supervision and Administration of Medical Device Manufacturing. For imported devices, a change of a manufacturing address abroad is a more complex process that requires the submission of more information and a longer timeline.

licence, and does not include any manufacturing facility licence. Accordingly, it is easier to transfer the imported drug or device licence as long as the transferee meets the requirements of a new applicant or licence holder for the China imported drug or device licence (e.g., it must be a manufacturer that holds the foreign marketing authorisation that provided the basis for the CFDA to grant the China licence).

Suspension or revocation of approvals

The CFDA can suspend or terminate a clinical trial, or suspend or revoke a marketing authorisation if there are serious product safety issues, or if the manufacturer fails to comply with associated regulatory requirements. In comparison with many other regulatory schemes, the Chinese CFDA has many more grounds to suspend or revoke an approval. First, the marketing authorisation needs to be renewed periodically, every five years for drugs and devices. Every year, the CFDA decides not to renew many products, based on various grounds set out under the law. The PDR, for example, provides in Article 126 that:

> *In any of the following circumstances, a drug shall not be re-registered [if]:*
> *(1) the application for re-registration is not made prior to the expiry date;*
> *(2) the relevant requirements set by the State Food and Drug Administration when approved for marketing are not met;*
> *(3) the Phase IV clinical trial is not completed as required;*
> *(4) the adverse drug reaction monitoring is not conducted in accordance with regulations;*
> *(5) there are uncertain therapeutic efficacy, serious adverse reaction or other factors harmful to human health upon re-evaluation by the State Food and Drug Administration;*
> *(6) the drug approval documents shall be withdrawn in accordance with the provisions of the Drug Administration Law;*
> *(7) the production conditions prescribed in the Drug Administration Law are not met;*
> *(8) the obligation of observation period is not fulfilled in accordance with regulations; or*
> *(9) there are other circumstances not in conformity with relevant regulations.*

For devices, a renewal will not be granted if (1) the filing of the application is not timely; (2) compulsory standards for the medical device have been revised and the device fails to meet the new standards; and (3) specific conditions related to medical devices needed for treating rare disease or for public health emergencies are not met.[54]

Second, there are more types of non-compliance that can trigger licence suspension or revocation in China. For example, the DAL provides for the revocation of drug approval licences on various grounds, including:

a if there is production or sale of counterfeit or substandard drugs;[55]

54 Article 55 of the RSAMD.

55 Articles 74 and 75.

b if there is non-compliance with customs rules for imported drugs;[56] or
c where the labels do not meet applicable requirements.[57]

The RSAMD provide for the re-evaluation and potential revocation of medical device licences when:

a new developments in science and technology raise questions about the safety and effectiveness of the device;
b adverse event reporting raises questions about the safety and effectiveness; and
c any other circumstances that the CFDA determines warrant a re-evaluation.[58]

The revised RSAMD provide that obtaining a licence via fraudulent or corrupt means is grounds for revocation of the licence.[59] Other activities that constitute impermissible marketing of devices or marketing of devices known to be unsafe or not in compliance with standards may result in fines, seizures, disgorgement, and, in certain circumstances, blacklisting from the industry.

viii Manufacturing controls

Drug or device manufacturing facilities located in China must be approved. Class II and III facilities require a licence, whereas Class I device facilities submit a notification to local food and drug regulatory authorities. For drugs, any proposed establishment of a facility must be approved by government agencies responsible for economic planning, and by the PFDA for potential ability to meet GMP requirements. Upon completion of the facility construction, the facilities must pass GMP inspection and receive a GMP certificate before they can be issued a drug or medical device manufacturing licence. Product sample testing by government labs is required as a part of the review and approval of clinical trial and marketing authorisation processing, and pre-approval inspections are required, all designed to ensure GMP compliance.

All device enterprises must comply with quality management rules (i.e., GMP and product standards). Class II and Class III device facilities must be verified as device GMP-compliant before a local authority will issue a manufacturing licence. This requires a compliance inspection.[60] If any manufacturer is found to be non-compliant with rules, and does not correct the violation, it can be fined or shut down.[61]

Contract manufacturers must be similarly GMP-compliant, and hold the requisite manufacturing licence. Under some circumstances, in which the CFDA has determined that the products present heightened risk, such as in the case of implantable

56 Article 81.
57 Article 86.
58 Article 51 of the RSAMD.
59 Article 64 of the RSAMD.
60 Article 10 of the Measures for the Supervision and Administration of Medical Device Manufacturing.
61 Article 67 of RSAMD; Article 67 of Measures on the Supervision and Administration of Medical Devices.

devices, biologics, psychotropic drugs, or narcotic drugs, the agency will not permit contract manufacturing.[62]

Transfer of ownership of a manufacturing site requires a supplementary application to amend the information on the manufacturing licence. Some amendments require administrative review (such as changes to the company name, legal representative, ownership type and registered address), or substantial review (such as changes to the head of the manufacturing site, the manufacturing scope and manufacturing address).

ix Advertising and promotion

Drugs

Advertising

China requires CFDA pre-approval of all drug advertising and prohibits any direct to consumer advertising of prescription drugs. The term 'advertising' is broadly defined.[63] Article 3 of the Detailed Rules on Implementation of Administration of Advertisements (2004), contains a generally-phrased list of the various media and promotional activities as examples. The drug-specific advertisement requirements and prohibitions are provided in a number of Chinese laws and regulations, including the Measures for Review of Drug Advertisement (Advertisement Measures), and the Standards for Drug Advertisement Review and Release (Advertisement Standards), both of which were promulgated jointly by the CFDA and the SAIC in 2007.

The Advertisement Measures require provincial FDA review and approval of all drug advertisement materials except those that contain only the drug name. Article 4 of the Advertisement Measures provides that advertisements of prescription drugs can only run in CFDA-approved medical journals (currently, the CFDA has approved about 557 such journals).

The prohibition on consumer advertising of prescription-only drugs also prevents many indirect advertising activities, such as sending journals or reprints to the public, or sponsoring events using the prescription drug name as the event name, or any other means of advertising to the public.

Upon approval, drug advertisements are given an approval number, which appears on the advertisements. Advertisement approval is valid for one year only and no change is allowed to an approved advertisement. Upon the approval's expiry, or if any change is needed to an approved and unexpired advertisement piece, a new advertisement application must be filed and new advertisement approval obtained. The CFDA has posted on its website all advertisements that have been approved and those against which there has been enforcement.

62 Article 12 of the Regulations on Drug Contract Manufacturing (2014).

63 Under the Advertisement Law of China (1994), which applies to all advertisement including drug or device advertisement, the term advertisement is defined in Article 2 as 'any commercial advertisement, which a commodity or service provider bears the costs for, through certain media or forms, directly or indirectly introducing their commodities being sold or services being provided'.

The penalties for unapproved changes to an approved advertisement include immediate revocation of the advertisement approval, and rejection of any advertisement application for the subject drug for one year. Heavier penalties would apply in the event that an illegal advertisement expands the scope of the indications or primary therapeutic function, exaggerates efficacy or seriously deceives and misleads consumers. Such heavier penalties include the provincial FDA suspending the sale of the subject drug within the province that has jurisdiction, and ordering the drug company to run corrections regarding the advertising concerned.

Promotion

The term 'promotion' is not defined under Chinese law. Any activity related to a drug is promotional, if the intent is promotional, as that term is commonly understood (i.e., where it is intended to further the acceptance and sale of the drug). This includes a broad array of product launch activities and associated materials. Scientific information exchange, including exchange of off-label information, can be viewed as non-promotional when conducted appropriately, because the intent is to advance science and medicine through the exchange of scientific information between medical professionals, rather than to further the acceptance or sale of a drug.

China prohibits off-label promotion through Drug Instruction or Drug Label. The prohibition against off-label advertising is set out in Article 6 of the Advertisement Standards:

> *The advertisement content relating to the indications or the primary therapeutic functions must be consistent with the drug instructions approved by the CFDA, must not expand or maliciously conceal, and must not contain any theories, viewpoints, or similar contents that are outside the drug instructions.*

Article 3 of the Regulations on Administration of Drug Product Instructions and Labels (CFDA, 2006) requires that: 'drug instructions and labels shall be approved by CFDA, the labels shall be based on the drug instructions, and the contents of the labels shall not exceed the scope of product instructions, shall not contain wordings or symbols that imply therapeutic effectiveness, misleading use, or inappropriate promotion'. The Drug Administration Law of China also prohibits off-label promotion through other means, such as labelling materials, including the spoken words or written or video materials used by sale representatives in promotional discussions with physicians.

Devices

Device advertisements also currently require pre-approval. Regulation of advertising and promotion of medical devices is somewhat similar to those for drugs as described above. The rules for advertising and promotion of medical devices are set out in several regulations, such as the RSAMD, the Measures on the Examination of Medical Device Advertisements (2009) and the Standards on the Examination and Release of Medical Device Advertisements (2009). Now that the RSAMD have been completely revised, an amendment to device advertisement rules is possible.

x Distributors and wholesalers

China requires licensing for a company to engage in the retail or wholesale distribution of drugs that are manufactured by other companies. No such distribution licensing is required for a drug manufacturer to distribute the drugs that it manufactures for itself, provided it has obtained a CFDA drug registration and approval number. Similar to licensing of drug manufacturing facilities, the distributor must meet: the economic planning requirements (for a retail distributor or pharmacy, for example, factors include the number of residents for the area to be served, the public transportation available to the residents and actual local demand); and the ability to meet quality requirements, as evidenced by the passing of a good supply practice (GSP) inspection and receipt of a GSP certificate. Distribution of drugs via the internet is also restricted and requires permissions.

A similar system of device distribution licences also exists for Class III medical devices. Distributors of Class II devices no longer need a licence, but those distributors must submit a notification to their local municipal governments. In either case, the entity must certify that it has appropriate premises, storage conditions and quality management systems and personnel for its scope of operation.[64] The CFDA also finalised GSPs for devices in December of 2014, which became effective as of their release date.[65]

xi Classification of products

The CFDA classifies drugs as prescription drugs or over-the-counter (OTC) drugs, and requires the CFDA's review and pre-approval for both. For the purposes of sale, the CFDA further classifies OTC drugs into Type A or B, where Type A drugs can be sold only by pharmacies or distributors that have received drug wholesale or retail distribution licences, and Type B drugs can be sold at most retail places, such as convenience or grocery stores. Prescription drugs can only be advertised on CFDA-approved medical journals, while OTC drugs can be advertised on public media such as TV and radio stations.

The CFDA has not set up prescription or non-prescription classifications for medical devices.

xii Imports and exports

Imported drugs or medical devices for marketing in China must be pre-approved by the CFDA and fully comply with the applicable regulations by the CFDA and the Chinese customs before they can be imported into China for distribution and sale. Additional requirements, such as special import or export permits, are required for narcotic or psychotropic substances.[66] Drugs that are imported for processing and re-export do not require CFDA pre-approval. Only provincial FDA notification is required for such

64 Articles 29–31 of the RSAMD.

65 Article 66 of Medical Device Good Supply Practices, available at www.cfda.gov.cn/WS01/CL0087/110920.html.

66 Article 45 of the DAL.

products provided they will not be sold or used in China.[67] Additional testing at the border may be required.[68]

The CFDA generally does not impose the same requirements for export of drugs or devices and relies instead on the regulatory oversight of the country where the drug will be exported. Manufacturers of exported drugs and certain devices must still obtain a manufacturing licence and comply with good manufacturing practices and standards, as well as submit a filing to their local government.[69] There are exceptions for nine types of drug[70] and two types of device,[71] which the CFDA has placed into the catalogue of drugs and devices subject to full CFDA supervision.[72] In addition, special export permits are required for the export of some narcotics or psychotropic substances.

xiii Controlled substances

China exercises heightened control over narcotics and psychotropics. The State Council promulgated the Rules on the Administration of Narcotics and Psychotropics in 2005, and the CFDA, the Ministry of Public Security, and the Ministry of Health recently jointly issued the revised Catalogue of Narcotics (2013) and the revised Catalogue of Psychotropics (2013). Special heightened control is exercised by multiple government agencies over the growing of plants where narcotics or psychotropics are extracted, and the clinical trial, manufacturing, transportation and distribution of narcotics and psychotropics. For example, government agencies set the total amount of narcotics and psychotropics needed annually, while the CFDA then sets the annual production plan based on the current supply and stockpile, and the CFDA and the department of agriculture together set the annual growing plan. Special permits are given only to limited entities to study, produce, and distribute narcotics and psychotropics.

xiv Enforcement

Enforcement against violations of drug or medical device requirements is undertaken by the FDAs at national, provincial and lower local levels, with cooperation from other government agencies such as SAIC, NHFPC, and the public security bureaux (China's police force) at all levels of government. Routine and for-cause inspections are the primary means of detecting actual or suspected violations, and complaints from

67 Regulations on the Administration of Drug Processing for Export (2003).

68 Administrative Measures for the Inspection and Supervision of Imported Medical Devices (2007).

69 Article 3 of the Administrative Regulations on Filings for Contract Manufactured Drugs for Foreign Enterprises (2005); Article 70 Administrative Measures on the Manufacturing of Medical Devices (2014).

70 Gentamicin, atorvastatin, sildenafil, oseltamivir, cefoperazone, glycerine, heparin, artemisinin and traditional Chinese medicine in finished dosage form and indicated for erectile enhancement.

71 Glucose-testing strips and condoms.

72 Notice on Implementing Catalogue Administration on certain drugs and devices for export (2008), available at www.sfda.gov.cn/WS01/CL0245/33456.html.

competitors are often the triggers for the for-cause inspections. The CFDA is also considering the adoption of comprehensive regulations on unannounced inspections for drug manufacturers.

The focus of inspections can include many compliance requirements and activities, such as those targeting GxPs (GLP, GCP, GMP, GSP), data integrity, conflicts of interest, bribery, violative advertisement and off-label promotion. The penalties include revocation of licences and certificates, which can be imposed (see Section II.vii, *supra*) on post-approval controls, in many more situations than in the United States. Other penalties include administrative fines, seizures of product, disgorgement of profits and blacklisting of companies and individuals. Monetary penalties tend to be lower than in the United States. Criminal liability can be imposed for many violations, and disbarment from engaging in drug or device work is possible. Production or distribution of counterfeit medicines as defined by the DAL may be subject to life in prison or the death penalty if the violation causes death or especially serious harm.[73]

III PRICING AND REIMBURSEMENT

Pricing for drugs is determined by either the government or the market, depending on whether a drug falls within the scope of drugs or devices that are covered and reimbursed by government insurance programmes or other special circumstances (e.g., blood products, vaccines, contraceptives). In these circumstances, the government will either set the prices or guide the prices by requiring the setting of a maximum retail price. In addition to pricing controls, to get their drugs distributed in state-owned hospitals, where most patients are seen, manufacturers must engage in bidding through their distributors in localities. These processes or price-setting and local bidding keep the prices of most drugs lower. In some circumstances, the government will require information from the manufacturer on costs to determine prices. China has been more carefully scrutinising the information that manufacturers provide to the government for price-setting.

Most insurance is through state plans. The government operates three basic insurance programmes: one for urban employees, one for urban non-state-employed residents and one for rural residents, covering nearly 90 per cent of the nation's population. Covered drugs for the urban plans are included in the National Reimbursement Drug List (NRDL), with a total of 2,151 drugs in its most recent version. The covered drugs for the rural plan may vary by province.

The NRDL is categorised into A and B lists. Drugs on List A are the National Essential Drug List, and are fully reimbursable in any province. Drugs on List B are only partially reimbursable under various insurance schemes at the provincial level. Pricing for the drugs on the NRDL are determined by government agencies based on various factors, including cost of production, clinical need, and supply and demand. The pricing and coverage decisions are taken primarily by the NDRC and its local counterparts (the pricing bureaux), as well as the Ministry of Human Resources and Social Security. Drug manufacturers and distributors are required to report various production costs

73 Article 141 of the Criminal Code of the People's Republic of China.

and sales information to the government agencies, and based on such information, the government agencies decide on the prices applying complex formulae.

A similar pricing system exists for medical devices. In some localities, the government will set a maximum retail price for devices. The manufacturer reports information about its costs to the government and is then permitted a certain markup that is set by the government.

As with drugs, coverage by the national plans and reimbursement rates for medical devices are set by a combination of central and local government agencies. Medical institutions (i.e., hospitals and clinics) acquire devices through restricted procurement processes.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Administrative and judicial remedies are available in China to appeal agency decisions and redress illegal government practices. Administrative regulations are rarely challenged in the courts for alleged defects in the underlying authority or rule-making procedures because China's Administrative Litigation Law prohibits 'abstract' challenges of this sort to the validity of administrative rules. Most efforts to formally challenge the CFDA focus on challenging concrete CFDA administrative decisions instead. Processes are available for both administrative reconsideration and judicial review of administrative decisions, but it may be difficult to win controversial cases in court in the absence of a clear violation by the agency of laws, regulations or its own rules. Statistics from China's Office of Legislative Affairs show that in 2013 the CFDA was involved in a total of 150 administrative reconsideration cases, and only one administrative lawsuit was brought against the agency.[74]

i Administrative reconsideration

When an applicant is not satisfied with a government agency's decision, the applicant may file an administrative reconsideration request for review by either the government agency itself or its supervising ministry or department within 60 days.[75] To file an administrative reconsideration request challenging an CFDA decision, the applicant must have legal standing to do so. The complaint must name the respondent and the specific decision the applicant is challenging.[76] Permissible grounds for reconsideration are:

a the agency's fact-finding on major issues is incorrect and evidence is inadequate to support the decision made;
b the law was erroneously applied;
c the agency violated relevant statutory procedures;

74 2013 National Administrative Reconsideration and Administrative Litigation Statistics and Data Table, available at www.chinalaw.gov.cn/article/jggz/fztjxx/201403/20140300395412.shtml.

75 Administrative Reconsideration Law (1999).

76 Administrative Reconsideration Measures of the CFDA (2013).

d the agency exceeded its authority or abused its power; or
e the decision was obviously inappropriate.

A special division in the CFDA, the Administrative Reconsideration Office (ARO), is responsible for handling administrative reconsideration requests to challenge decisions made by the CFDA itself or its local offices. For complex cases and cases involving a challenge to underlying laws or regulations, the Administrative Reconsideration Committee (ARC), which consists of the Commissioner and Deputy Commissioners of the CFDA and ranks higher than the ARO, will hear the case.

The ARO or ARC will examine the request and decide within five days if it meets the requirements for reconsideration.[77] If so, it will be accepted for review and the ARO or ARC is obliged to render a decision within 60 days. If the situation is complicated, the time for review may be extended by a maximum of 30 days. The ARO or ARC may affirm the administrative decision, or overturn it and remand the matter to the government agency with instructions to take either a specific or an alternative administrative act. The decision of the ARO or ARC is legally effective upon the signature of the head of the CFDA.[78] The applicant can appeal the ARO or ARC's decision to the State Council, whose decision is final, without the availability of judicial review.

ii Judicial lawsuit

If an applicant decides not to appeal the ARO or ARC's decision to the State Council, it may bring a judicial lawsuit in the People's Court against the ARO within 15 days after the time limit for reconsideration expires.[79] If the People's Court finds that any of the following conditions are met, then the administrative act must be annulled or partially annulled or the defendant must be ordered to take another alternative administrative act:

a the major evidence was inadequate;
b the administrative agency erroneously applied the law or regulations;
c the administrative act violated legal procedures;
d the administrative act exceeded authority; or
e administrative power was abused.[80]

77 Article 17 of the Administrative Reconsideration Law; see also Article 48 of the Regulations on the Implementation of the Administrative Reconsideration Law (2007).

78 Article 20 of the Administrative Reconsideration Measures of the CFDA.

79 Article 38 of the Administrative Litigation Law (2014).

80 Article 54 of the Administrative Litigation Law; see also Article 6 of the Provisions of the Supreme People's Court on Several Issues Concerning the Hearing of Administrative Cases of International Trade (2002). Similar interpretations can be found in Provisions of the Supreme People's Court on Several Issues Concerning the Application of Laws in the Hearing of Anti-Dumping Administrative Cases (2002) and Provisions of the Supreme People's Court on Several Issues Concerning the Application of Laws in the Hearing of Countervailing Administrative Cases (2002).

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

China has enacted laws and regulations to prohibit bribery, kickbacks or other inappropriate financial relationships or sponsorship. The DAL contains these provisions and penalties for violations could include revocation of the drug or medical device approvals, civil fines and criminal penalties. In addition, the SAIC administers regulations against commercial bribery. Bribery cases may also be handled through the criminal justice system. Scrutiny of these activities has grown substantially in the past two years since the Chinese government launched anti-bribery investigations of foreign drug manufacturers.

The fallout from those investigations has resulted in much more significant scrutiny of the relationships between drug companies and health-care providers by regulators in China. The NHFPC issued a policy of 'Nine Prohibitions' (or bad acts in the health-care system) that would be the focus of government scrutiny and enforcement resources, as well as blacklisting rules meant to curb ethical abuses in the health-care sector. The Nine Prohibitions include:

a no linkage between health-care provider incomes and profits from drug sales or medical services;
b no rebates for prescribing medicine or referrals for services or drugs;
c no overcharging of patients;
d no accepting illegal donations;
e no illegal advertisements or promotion of drugs, devices, food or other products by medical institutions or health-care providers;
f no collation of statistics for commercial purposes or personal gain by health-care providers;
g no private buying or selling of drugs, devices or other equipment by health-care providers;
h no acceptance of kickbacks or commissions from health-care companies or engagement in entertainment activities provided by those companies; and
i no solicitation or acceptance of financial benefits from patients.[81]

In late 2013, nine agencies, including NHFPC and the CFDA, issued a joint opinion (a blueprint of sorts) intended to create higher standards for ethical conduct by physicians and other hospital personnel in their dealings with the drug industry. The opinion also mentioned higher standards for safety for medical devices but singled out corruption associated with drugs as the primary target.

Scrutiny in this area continues to be very significant and regulatory reform is continuing. In late 2014, the NHFPC issued measures on clinical research projects at medical and other health institutions, which among other things, called for stronger

81 Notice on Improving the Medical Health-Care Workstyle and Establishing the Nine Prohibitions, available at www.moh.gov.cn/jcj/s7692/201312/09bd7a8be8f8420d91997a0041aa868e.shtml.

clinical research and ethics committee management of these projects, and guidelines for financial management intended to prohibit payments directly to investigators.[82]

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Compensation can rely on provisions specifically on drugs and devices in the Tort Law, and perhaps on provisions in other laws, such as the Consumer Protection Law and the Product Quality Law. Compensation is available only when the product is defective or not made according to compulsory national standards. Drugs or medical devices can still cause injuries in the absence of product defects or medical malpractice, but no special strict liability has been set up for compensation under such circumstances.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

China's Anti-Monopoly Law (AML) took effect on 1 August 2008 and enforcement has become increasingly prominent in the health-care industry in the past three years. Three enforcement agencies are responsible for enforcing the law: the Anti-Monopoly Bureau of the Ministry of Commerce (Mofcom), the SAIC and the Price Supervision and Anti-Monopoly Bureau of the NDRC.

Mofcom reviews 'concentration' – defined as a merger, an acquisition of assets or equity that confers control over another company, or an acquisition of a decisive influence over another company through contract or other means. The NDRC and SAIC handle price-related and non-price-related violations respectively in connection with monopoly agreements and abuse of dominance.

Both Mofcom and the NDRC have bought enforcement actions against companies in the life sciences sector. Mofcom imposed conditions on two transactions involving life science companies – *Pfizer/Wyeth* (2009) and *Novartis/Alcon* (2010). In the *Pfizer/Wyeth* case, Mofcom conditioned its clearance on Pfizer's commitment to spin off, under the supervision of a trustee, its swine mycoplasma pneumonia business, including tangible assets and intellectual property rights necessary to compete. Novartis, rather than facing a structural remedy like Pfizer, was barred from selling its Infectoflam product or similar opthalmological anti-infective products in China and required to terminate within 12 months a distribution agreement it had with Hydron (the largest contact lens distributor in China) regarding Novartis's contact lens-care products, as a condition for the approval of its acquisition of Alcon. Hydron had been appointed as the sole distributor for Novartis in China since 2008 and Mofcom was concerned that post-transaction, the distribution agreement could lead to coordination in prices, quantity and sales regions between Novartis and Hydron.

82 Administrative Measures on the Development of Clinical Research Projects at Medical Health Institutions (2014), available at www.nhfpc.gov.cn/yzygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml.

In November 2011, the NDRC announced that it was fining Shandong Weifang Shuntong Pharmaceutical Co Ltd (Shuntong) and Weifang Huaxin Medicine Trade Co Ltd (Huaxin) a total of about $1.1 million – the first AML fines levied by NDRC – for monopolising bulk sales of promethazine hydrochloride, a key ingredient in the production of compound reserpine tablets, a popular hypertension medication in China. In its statement, the NDRC stated that Shuntong and Huaxin entered into contracts with the only two producers of promethazine hydrochloride, the terms of which prohibited the producers from selling to third parties without Shuntong's and Huaxin's approval. After gaining control over the raw material, the companies allegedly increased their prices dramatically. The NDRC fined the companies for abusing their dominant positions in violation of the AML.

In 2013, the NDRC stepped up its enforcement of the anti-monopoly law, particularly in the area of pricing of pharmaceutical drugs and infant formula. The agency conducted investigations into the pricing practices for products of over 60 pharmaceutical companies, and there were signs that the medical device firms would be next. In some respects, these pricing investigations were overshadowed by commercial bribery cases in the health-care sector.[83]

The details of the investigations were somewhat sparse. Some of the firms investigated stated that they were pressured to lower prices in response to government inquiries and they were not permitted to present evidence to NDRC in their defence.[84] They were not permitted to bring counsel, particularly counsel from foreign law firms, to the meetings with NDRC. Ultimately some of the firms reduced their prices and paid high fines. For example, six infant formula companies paid over $108 million in fines.[85]

Also in 2013, a Shanghai high court ruled in favour of a plaintiff in the first successful private suit under the anti-monopoly law for vertical price-fixing. The case, which involved Johnson & Johnson's device business for surgical sutures in China, related to a distribution contract setting minimum resale prices. The court found that the plaintiff had carried its burden of showing that the defendant's conduct created a vertical restraint that had an anti-competitive effect. The court analysed (1) whether there was sufficient competition between manufacturers in the market; (2) whether the defendant exercised market dominance; (3) the defendant's motives in entering into the distribution agreement; and (4) whether the anti-competitive effects of the conduct outweighed any negative effects on fair competition. The court awarded approximately $85,000 in lost profits as a result of its finding of these violations.[86]

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83 Benjamin Shobert and Damjam P. DeNoble, *Understanding China's Antimonopoly Investigations*, China Business Review, 30 March 2014, available at www.chinabusinessreview.com/understanding-chinas-antimonopoly-investigations/.

84 USTR, 2014 Report to Congress on China's WTO Compliance, at 19 (2014).

85 China Fines Six Companies for Baby Formula Price Fixing, CNN, 7 August 2013, available at http://money.cnn.com/2013/08/07/news/china-baby-formula/.

86 Chunfai Lui & Stephenson Harwood, *A Landmark Court Ruling in China: Resale Price Maintenance As Examined in the Johnson & Johnson Case*, CPI Antitrust Chronicle, available at https://www.competitionpolicyinternational.com/file/view/7010.

ii Transactional issues

Government approval is a key issue to bear in mind for any M&A or joint venture deals in China. Depending on the nature of the target company and the deal structure, different types of approvals may be required. For example, an acquisition of an onshore Chinese target company will require approvals from a number of government agencies including the Ministry of Commerce (or their local counterparts) and the NDRC. In addition, if structured as an asset acquisition of a Chinese pharmaceutical business, additional approval from the CFDA is required for re-issuance of the relevant operating permits (such as the drug manufacturing licence or the drug distribution licence, as the case may be).

Joint ventures are commonly used for Western life sciences companies seeking to enter the Chinese market. Approval by the Ministry of Commerce or one of its local counterparts is required for setting up joint ventures. In addition, if the joint venture wishes to engage in business activities requiring special licences, such licences must be obtained before the relevant activities may be included in the joint venture's business scope. By way of background, a corporate entity in China is only permitted to conduct business activities listed in its business scope on its business licence issued by the government authority. This is particularly relevant for companies in the life sciences space because many activities in this space require specific licences, such as a drug manufacture licence or drug distribution licence. In recent years, the Chinese government has limited the issuance of new drug distribution licences by significantly raising the threshold requirements, making them very difficult to obtain.

Apart from M&A and joint ventures, complex life sciences transactions commonly seen in the United States and Europe, such as licensing and collaboration arrangements, are rare in China. This is due to the fact that China's life sciences industry has traditionally been dominated by generic players and there are simply few innovative assets in China. This is now beginning to change – fostered by government policies encouraging innovations in biotech, increasing numbers of innovative biotech companies have sprung up in China. At the same time, more Chinese generic companies seek to grow into the innovative side of the business by partnering with Western companies. As a result, the number of licensing and collaboration deals has increased steadily in the past few years.

VIII CURRENT DEVELOPMENTS

China is in the middle of revisions of its framework statutes in the drug, food and cosmetics spaces. The revision of the RSAMD was also part of this overhaul of food and drug law and regulation. Other reforms are going on in advertisement, price and health-care law and regulation, and those reforms will also have a significant impact on the drug and device companies doing business in China.

These reforms involve trends that have spanned the different spaces. For example, the CFDA is experimenting with pre-market notification (versus licensing) systems in the device, cosmetic and dietary supplement areas. This is part of a larger policy trend away from unnecessarily cumbersome pre-approval processes. In addition, the government is re-examining its pricing and reimbursement practices. In some respects,

it is making those practices more market oriented, but that push for market reform is balanced by pressures to keep health-care costs low and affordable. Also, the government has held fast to the 'imported versus domestic' distinction in most spaces and it is not yet clear whether and when it will consider abandoning that distinction. Preferential review status, pricing controls and reimbursement avenues may be available only to domestically manufactured products in certain circumstances.

The following are some of the more noteworthy changes that may take place in the next two to three years. An amendment to the DAL has been in the pipeline for some time, and hopefully will be completed and enacted in the next few years. This amendment is to likely establish a more comprehensive system for the regulation of drugs including biologics that is aligned with the regulatory schemes and practices in developed countries, and will pave the way for amendments to the key regulations such as those governing the registration of drugs.

Separate and apart from the planned amendment of the DAL, a proposed amendment to the PDR was issued in 2014. The latest proposed drafts of the PDR revision would further remove the CFDA from patent enforcement, leaving it to the generic applicant to make its own determination as to whether its application is infringing. Although the CFDA is technically not permitted to issue the generic drug licence if there is an infringement, there would be no mechanism to enforce that responsibility. The CFDA is also considering expanding the scope of the new-drug monitoring period to allow those applicants whose clinical trial applications have been accepted for review to proceed when a new-drug monitoring period is imposed. (Currently only those with approved CTAs are allowed to proceed.) Also, as noted above, the amendment to the PDR would also create a procedure to amend some items in the CTA prior to Phase III.

For both drugs and devices, increased enforcement of GMPs and GSPs will be important. Drug and device GMPs have both recently been updated. As noted above, the CFDA finalised its first set of GSPs for medical devices in December 2014. Monitoring of distribution and supply chains will also be important to curb drug counterfeiting. The CFDA has announced that it will complete the implementation of its electronic monitoring system for manufacturers and distributors by the end of 2015. This system will require barcodes on different layers of drug packaging and the transmission of information and observable issues concerning their movement through the supply chain.

Clinical trial reform is likely to remain a priority area. Overall, the policy direction is to improve the design of trials and adherence to GCP, as well as implement stronger ethical safeguards to protect subjects and prevent corruption. The CFDA is re-examining its policy on multi-regional clinical trials in China and looking to provide stakeholders with guidance on the design and implementation of those trials and the potential to use them to support registration applications. In addition, the CFDA is working on building a stronger specialised system for medical device trials, including regulations to accredit certain hospitals to conduct those trials and good clinical practices for device trials.

China is also continuing to reform the areas of drug and device pricing and reimbursement. Currently the NDRC is considering a plan that would abandon some of the price controls on drugs on the national insurance plans and permit their prices to be set by the market. The NHFPC is also considering revisions to its reimbursement policies that would permit generics and innovative drugs to be reimbursed at similar rates.

Some localities are also re-examining or drafting procurement or pricing regulations for medical devices. In addition, the NHFPC has been advocating that hospitals and clinics increase their procurement of domestically manufactured medical devices to promote the development of domestic industry (imports dominate in the medical device sector) and keep prices of devices low. It is unclear how all of these proposed reforms will come together. To date, little information related to the reforms has been officially released in the public domain.

The timelines for these reforms are as yet unclear. While it would not be surprising to see movement on the aforementioned proposals in either 2015 or 2016, delays are possible because these are very controversial areas.

Appendix 1

ABOUT THE AUTHORS

SHAOYU CHEN

Covington & Burling LLP

Shaoyu Chen is a partner at Covington & Burling LLP, based in the Beijing and Shanghai offices, and is the managing director of the firm's China food and drug practice. Mr Chen has 15 years of experience in food and drug law, including serving as assistant chief counsel at the US Food and Drug Administration Office of Chief Counsel, as senior counsel at California-based Amgen Inc, and as chief compliance counsel for GE Healthcare China. Mr Chen represents pharmaceutical, biotechnology, medical device, food, dietary supplement, and cosmetic companies in matters involving the China CFDA, the US FDA and other government agencies; he assists clients on legal and regulatory issues related to CFDA and FDA oversight, including those pertaining to pre-clinical research, clinical trial, marketing approval, advertising and promotion, manufacturing GMP, drug safety, and import and export. Mr Chen also advises companies on other legal matters, such as those related to collaboration, anti-unfair competition and general corporate affairs and business conduct. Mr Chen received his undergraduate degree from Peking University, and his Juris Doctor from the University of Nebraska, where he served as executive editor of the *Nebraska Law Review* and graduated with distinction.

JOHN BALZANO

Covington & Burling LLP

John Balzano is a special counsel in the New York office of Covington and Burling. Mr Balzano's practice focuses on advising food, dietary supplement, drug, medical device, and cosmetics companies on issues of regulatory compliance, strategy and advocacy in China. His practice spans the life cycle of these products, from the R&D stage of development through to post-marketing and promotional issues. Prior to coming to Covington, Mr Balzano taught Chinese law and regulation at both Yale Law School and Boston University Law School. He also worked with the China Law Center of Yale Law

School to run administrative law and food and drug law projects with various scholars and government agencies in China. Mr Balzano was also a litigation attorney, and he clerked for the Honorable Joette Katz of the Supreme Court of Connecticut and the Honorable Steven M Gold of the United States District Court for the Eastern District of New York. He received his JD and master's in East Asian studies from Washington University in St Louis and his bachelor of arts degree in East Asian languages and cultures from Columbia University.

COVINGTON & BURLING LLP
2301 Tower C Yintai Centre
2 Jianguomenwai Avenue
Chaoyang District
Beijing 100022
China
Tel: +86 10 5910 0591
Fax: +86 10 5910 0599
schen@cov.com

www.cov.com