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China Lifesciences Update and Predictions for 2017

January – December 2016

Contents

Overview

2016 saw important developments for the Lifesciences sector in China, including:

— The launch of anti-trust investigations by the National Development and Reform Commission (the 'NDRC') into the pharmaceutical and medical device sectors and the issuing of significant fines.

— Implementation of new policies and procedures by the China Food and Drug Administration (the 'CFDA'), including the food and drug traceability system, Approval Process for Medical Devices and Pilot Drug Marketing Authorisation Holder ('MAH') system.

— Confirmation by the CFDA on the completion of the legal framework for food and drug regulation by 2020.

In this update, we have collated the significant 'China Lifesciences Monthly Updates' for 2016 and set out our top 10 predictions for 2017.

In 2017, we expect developments on the anti-trust investigations, tightened supervision on anti-bribery, the new drug price regime, details on the implementation measures on the registration of biosimilars, the reform in social insurance, M-health and medical industry.

We will continue to closely monitor the developments in the Lifesciences sector in China and to provide you with regular updates on them through our free eAlert service, Law-Now.

We hope you find this update interesting and informative and if you have any specific questions on any of the developments mentioned, please do let me know.

With best wishes for the Year of the Rooster.

Kind regards,

Nick Beckett
Managing Partner, Beijing Office
T +86 10 8527 0287
M +86 186 1842 8030
E nick.beckett@cms-cmck.com

January/February

Unified Basic Medical Insurance System for Urban and Rural Residents to be established

On 12 January 2016, the State Council issued the Opinion on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents ('Opinion').

According to the Opinion, the new medical insurance system will ensure a more standardised practice is employed for the management of services throughout China, and aims to use medical resources efficiently in order to encourage the development of a sustainable and universal medical insurance system. In order to achieve these aims, the Opinion provides a number of initiatives which include provisions on the improved management of funds and selected agencies, a health insurance directory, security benefits and directions on unified coverage. Under the new medical insurance system, all insured persons will enjoy the same payment standards and scope of subsidies. The fund that the new system will provide will be predominantly used to reimburse out-patient and hospitalisation expenses.

Further opening of the Chinese lifesciences sector in 2016
The Notice of Health and Family Planning Working Essentials for 2016 ('Notice') was issued on 26 January 2016 by the National Health and Family Planning Commission ('NHFPC). Pursuant to the Notice, the government will reform China's medical system by improving the national health insurance system, improving services in the industry and promoting innovation in the Chinese pharmaceutical science and technology community.

Certain drug registration applications will be fast tracked in China

On 26 February 2016, the CFDA issued the Opinion on the Implementation of Priority Review and Approval to Resolve Backlogged Drug Registration Applications ('Opinion'). The Opinion established a priority review and approval process for specific drugs which significantly reduces the term of the registration period. According to the Opinion, new drug clinical trial applications, new drug market applications and generic drug registrations are entitled to priority review and approval, if the applications satisfy certain requirements.

NDRC fines pharmaceutical companies for drug monopoly

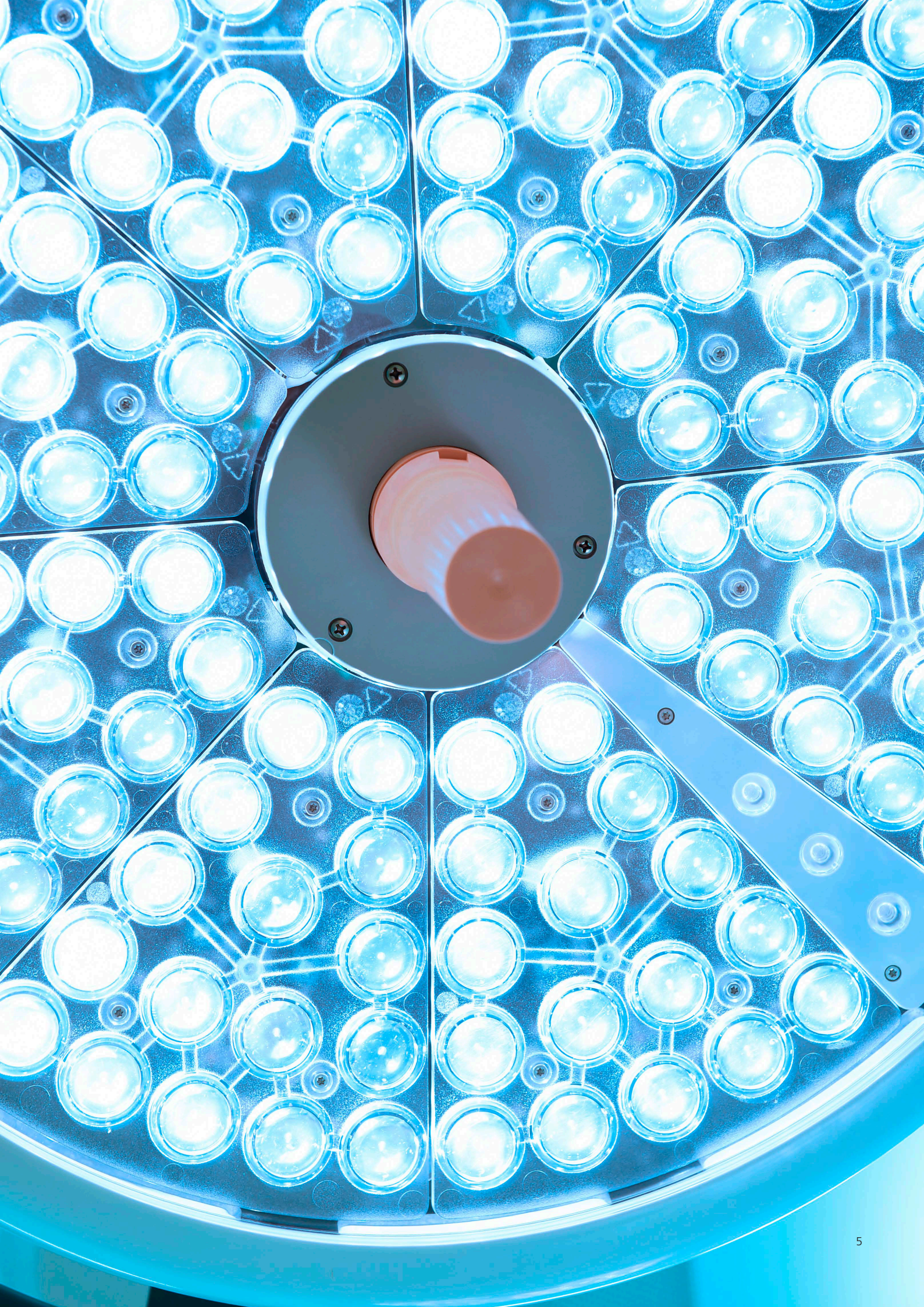
On 28 January 2016, the Anti-Monopoly Bureau of the NDRC fined five domestic pharmaceutical companies for monopolistic behaviour in drug pricing.

This was the first monopoly case since the reforms to the drug pricing regime came into power and it demonstrated that the authorities will be tough when it comes to protecting the affordability of medicines going forward. This focus may pose a potential risk for both domestic and international companies with regard to setting drug prices.

CFDA plans to reform evaluation and approval systems for medical devices

On 21 January 2016, the CFDA stated it pushed forward a system of evaluation and approval for medical devices. The key tasks to create the system are as follows:

- To strengthen quality management, establish and improve quality evaluation and an approval system;
- To optimise the evaluation and approval processes, improve the quality of the registration process;
- To encourage medical research and innovation, improve the innovation of working mechanism;
- To advance the management of medical device classification;
- To improve the management of medical device standards;
- To promote the supervision and management of clinical trials;
- To improve the ability to evaluate and approve at the provincial level.



March/April

China supports public complaints and reports regarding food and drug-related illegal acts

The CDFA published the Administrative Measures for Food and Drug Complaints and Reports ('Measures'). The Measures were implemented from 1 March 2016. The Measures compel citizens, legal persons or other organisations to report to the food and drug administrations at all levels if they suspect illegal acts are being committed by producers, operators and other subjects with regard to food safety. The media is also encouraged to publicise such illegal acts. The CDFA advocate real-name complaints and reports. However, if there are some complainants who are reluctant to provide their name, identity, contact information or other personal information, these people will not be forced to do so.

New Chemical Drug Registration Classification applied in China

On 4 March, the CFDA released the Reform of Classified Chemical Drug Registrations ('Reform') with immediate effect. According to the Reform, drug applications will be placed into one of the following five categories:

1. Innovative drugs which have never been marketed anywhere in the world;
2. Improved drugs which have never been marketed anywhere in the world;
3. Drugs which imitate innovative drugs that have not been sold within the territory of China, but have been sold outside of China;
4. Drugs which imitate innovative drugs that have been sold within the territory of China;
5. Drugs which have been marketed outside China.

According to the Reform, classifications one and two are defined as 'new drugs' and will enjoy a three to five year monitoring period, which is also a market exclusivity period during which no generic drug registration will be approved. In a similar way to the old classification regime, classifications three and four are defined as generic drugs and the fifth classification is defined as an import drug.

Drug Tracing System may replace current Drug Electronic Supervision System in China

The CFDA issued the revised draft Quality Control Standards for Pharmaceutical Distribution (GSP) (the 'Draft') which was open for public comment until 23 March 2016. According to the Draft, the basic principles and requirements of the new Drug Tracing System have been clarified; the term 'drug

electronic supervision' has been replaced with 'drug tracing'; all requirements regarding mandatory scanning and the electronic uploading of the monitoring code have been deleted or revised; and the requirement that computer systems must be available to implement an electronic drug supervision system has been deleted or revised.

Guidance on promoting the healthy development of the pharmaceutical industry

On 4 March 2016, the General Office of the State Council issued the Guiding Opinions on Promoting the Healthy Development of the Pharmaceutical Industry ('Opinion') The Opinion identifies seven main tasks for the pharmaceutical industry to focus on, including:

1. Strengthening technological innovation and enhancing core competitiveness;
2. Quicken quality improvement process and promote green and safe development;
3. Optimise the industrial structure, and improve the level of intensive development;
4. Develop modern logistics, and construct a credit system for medicine;
5. Create a favourable market for medicines;
6. Deepen cooperation with foreign enterprises, expand the scope for international development;
7. Foster new emerging enterprises, promote the cognitive development of the pharmaceutical industry.

Premier Li pledges support for pharma

On 5 March 2016, Premier Li announced that the government will focus on the coordination of reforms to alleviate patient burdens by unifying the urban and rural Basic Medical Insurance (BMI) schemes. The BMI reimbursement payment system will also be reformed to allow patients to be reimbursed for medical care outside of their home provinces. The public hospital reforms will be expanded into more pilot cities, with medical service pricing reforms and improving drug distribution among the key targets.

State Council request CFDA to focus on reform

On 29 March 2016, the State Council issued the Report on the Work of the Government, which requested the CFDA to reform the review system and the approval of drugs and medical devices, to encourage the development of family doctors and paediatricians and to accelerate and improve the unified and authoritative food and supervision system for drug safety.

CFDA grants priority reviews to two cancer drugs

The CFDA's Center for Drug Evaluation (CDE) released a press release setting out the recent decisions of an expert meeting on priority drug evaluations. Two cancer drugs – lenalidomide and afatinib – have been chosen for prioritised evaluation on the basis of an obvious clinical advantage over current treatments.

Naming Rules for Generic Names of Medical Devices came into effect

The CFDA issued the Naming Rules for Generic Names of Medical Devices ('Rules'), which came into force on 1 April 2016.

The key points are as follows:

- The Rules apply to medical apparatus and instruments sold and used in China;
- The names of generic drugs and medical devices shall be standardised, and be written in Chinese characters;
- Medical devices of the same type, that share the same or similar purpose shall have the same generic name;
- Generic names shall meet the related requirements of the Rules and shall exclude the nine prohibited items noted in the Rules, including 'personal names, enterprise titles, registered trademarks or other similar names';
- Generic names cannot be registered as a trademark.

May

50 percent decrease in drug prices after negotiation

The NHFPC announced the outcome of the first round of drug price negotiations ('Announcement'). According to the Announcement, new drug prices for Viread, Conmana and Iressa were agreed during the negotiations and discounted by more than 50 percent.

On April 25, the Notice of the Centralised Purchase of Nationally Negotiated Drugs ('Notice') was jointly issued by the NHFPC and other relevant authorities. The Notice aims to push forward the drug negotiation regime. This includes the manufacturing companies of the negotiated drugs ensuring the quality and supply of the drug, local authorities listing all negotiated prices at the Provincial Drug Centralised Purchase Platform and medical institutions purchasing drugs at the negotiated prices online.

CFDA seeking comments on the food and drug traceability system

On 27 April, the CFDA issued the Opinions on Further Improving the Food and Drug Traceability System (Draft for Comment) (the 'Opinion') which closed for public comments on 23 May 2016. The Draft aims to encourage enterprises to establish sound traceability systems which focus on supervision of all forms of food and drugs throughout the entire process. According to the Draft, food and drug manufacturers and distributors shall adopt appropriate approaches to record or identify sources of raw materials, buying and selling details, and destinations of products.

NDRC launched anti-trust investigation into pharmaceutical sector

The NDRC launched a new round of anti-trust investigations into pharmaceutical companies. One top US pharmaceutical firms had already been summoned for inquiry, and more foreign and domestic companies were called shortly after. The investigation is described as 'large-scale and systematic'; the aim is to collect evidence to see whether these companies have violated regulations regarding competition. The investigation focuses on strengthening competition enforcement in the pharmaceutical sector, but may also increase the pressure in the ongoing drug price negotiations.

NDRC launches Drug Price Investigation

The NDRC issued the Notice of Specific Inspection on Pharmaceutical Prices, which requires price control departments of all levels to carry out specific inspections on pharmaceutical prices. The inspections commenced on 1 June 2016 and ended on 31 October 2016. The areas of inspection included the price settings by pharmaceutical manufacturers, medical institutions, the Centre for Disease Control and Prevention, blood banks, the Drug Centralised Bidding and Purchasing Platforms, drug purchasing departments and related industry associations. The emphasis of these inspections was on those active pharmaceutical ingredients and drugs with unusual price fluctuations.

Tightened policy in private investment in medical institution

On 4 May, the Beijing Health and Family Planning Commission called for local authorities to organise comprehensive inspections to clean up contracted outsourcing businesses between hospitals and outside private businesses. The relevant agencies also called for strict examination of false medical advertisements.

On 17 May, the Shanghai Health and Family Planning Commission reaffirmed that doctors taking part in medical operations are registered, and that they are forbidden from working outside their registered workplace. Hospitals are prohibited from outsourcing the work of its departments to doctors who are not registered at that particular hospital or to outside private companies. Advertisements should strictly adhere to the Measures for the Administration of Medical Advertisements and the content should be true, legal and accurate.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June/July

Drug Tracing System replaces Drug Electronic Supervision System in China

The China Food and Drug Administration ('CFDA') issued the revised Good Supply Practice for Pharmaceutical Products ('GSP'). This updated GSP requires the distributor to build up a Drug Tracing System which can be used to search for, and find information on, the source of drugs, distribution of drugs and responsible parties. It has also set out stricter requirements on the personnel and equipment involved in storage, transport and supply of vaccines and drugs which require refrigeration.

CFDA further confirmed the implementation of MAH system

The CFDA issued a notice to all of its local branches to give further instructions on implementing the Pilot Drug Marketing Authorisation Holder ('MAH') system which was formulated in the Circular on the Pilot Program for the Drug Marketing Authorisation Holder System. During the pilot term (26 May 2016 to 4 November 2018), for qualified drugs, qualified drug R&D institutions and individuals in ten pilot areas can apply for a drug licence and to become a MAH. The applicant and holder will be liable for the clinical trial, drug registration, manufacturing and marketing processes. Qualified authorised manufacturing enterprises will be liable for the manufacturing process. The registration approval process is the same as the normal drug registration process.

CFDA solicits Public Opinion on the Prior Approval Process for Medical Devices

The CFDA issued the Circular Regarding Soliciting Comments Regarding Priority Review Designation Procedure for Medical Devices which closed for public comment on 20 July 2016. This Draft lists several circumstances under which medical devices can enjoy prior approval, which includes devices assessed as national major science and technology projects or key research and development programs; or devices which have brought about an obvious improvement in curing rare, difficult, elderly related or child related illnesses. The Draft also clarifies the relevant procedures and corresponding responsible government departments.

New Regulation on Vaccine Circulation and Preventive Inoculation

The CFDA and the National Health and Family Planning Commission ('NHFPC') jointly issued the revised Administrative Regulations on the Circulation of Vaccines and Vaccinations, which came into force as of the date of promulgation. According to the Regulation, overseas vaccine enterprises which export vaccines into China should find a Chinese agent to sell their vaccines and take on all of the responsibility under the Regulation on behalf of the foreign company, including for the quality of the vaccine. The agent is required to make record their activities with the local provincial FDA.

Stricter approval process for Baby Formula Products

The CFDA issued the Administrative Measures for Registration of Baby Formula Products which came into force on 1 October 2016. The Measure details the requirements for the application, evaluation and approval process; onsite investigations; and the renewal process. It also requires that the labels and instructions should be consistent with the content approved; misleading content, such as claims regarding the healthcare function of the product, that it will increase resistance or immunity to disease or protect intestinal functions, is prohibited; and the country of origin must be specified if the products are imported from overseas.

New measures for communication with CDE

The CFDA issued the Administrative Measures for Communication on Research, Development and Technical Evaluation of Drugs which came into force as of the date of promulgation. 'Communication' is defined as being between drug registration specialists and the Centre of Drug Evaluation's ('CDE') project manager and concerns key technical issues that are not included in existing guidebooks for drug research, development and evaluation. The Measure defines the types of communication meetings, procedures and requirements for the proposal, preparation, convening, postponement or cancellation of a communication meeting.

August/September

Administrative Measures for Drug Registration (Draft Revision) issued by CFDA

The CFDA released the Administrative Measures for Drug Registration (Draft Revision) which closed for public comment on 26 August. The Draft introduces several communication processes, and dispute resolution and information publication regimes which aim to improve the efficiency of the approval process and reduce the corresponding approval period.

Good Laboratory Practice for Non-clinical Laboratory Studies issued by CFDA

The CFDA issued the draft Good Laboratory Practice for Non-clinical Laboratory Studies (GLP) which closed for public comment on 18 October. The document contains 12 chapters and mainly sets out the definitions of certain terminologies, standards of practice, implementation of the research, management of documents as well as requirements for the staff, facilities and experiments.

CFDA to complete legal framework for food and drug regulation by 2020

The CFDA issued the Implementing Opinions on Comprehensively Strengthening the Rule of Law Construction in the Food and Drug Administration System on 8 August. The Opinion includes eight key tasks: accelerating the food and drug regulatory law system construction; implementing the streamlining government and optimisation of service; making administrative decision-making more scientific and democratic; adhering to strict, standardised and fair law enforcement; promoting food and drug legal education; effectively resolving social conflicts and disputes and improving the administrative capacity of the law enforcement officers.

Administrative Measures for Medical Device Recall (Draft for Comment) issued by CFDA

The CFDA issued the Administrative Measures for Medical Device Recall (Draft for Comment) on 1 September which closed for public comment on 30 September. The Draft aims to strengthen the supervision and administration of medical devices, and improve the safety and effectiveness of medical devices. The draft stipulates the definition of 'medical device recall', applicable circumstances of recall, the legal liabilities of relevant parties and two types of recall procedures: voluntary recall conducted by the manufacturers and compulsory recall ordered by the food and drug administration.

Authorities to take Joint Disciplinary Action against violator in Food and Drug industry

To establish and improve the joint disciplinary action in the food and drug industry, the CFDA and 27 other departments jointly issued the Memorandum of Cooperation in a Joint Disciplinary Action against Food and Drug Manufacturers and Business Operators with Serious Discreditable Conduct on 13 September. The Memorandum specifies the manufacturer, business operator and their executives would be the target of the actions. It also clarifies that CFDA will restrict the violator in its relevant business operation, while other authorities will restrict the violator's ability to get a loan, to be listed on the security market and attend government purchasing biddings.

October

MOHRSS will adjust catalogue of national basic medical insurance, employment injury insurance and maternity insurance

The Ministry of Human Resources and Social Security of the People's Republic of China (MOHRSS) issued the Adjustment Plan for Drug Reimbursement List (Draft for Comment) ('Draft') on 30 September. According to the Draft, drugs of high clinical value, and drugs treating serious diseases, children, emergency situations, and occupational diseases are most likely to be added.

NHFPC propelling the three negotiated drugs to be reimbursed

The NHFPC issued the Opinion on Making Negotiated Drugs and New Rural Cooperative Medical Reimbursement Well Connected on 30 September 2016. The provincial HFPCs are required to add the negotiated drugs into the drug reimbursement lists of the New Rural Cooperative Medical and Basic Medical Insurance managed by local HFPCs, which will consider the local economic development, funding level, medical service, and disease spectrum.

The State Council seeks public comments on the Implementing Regulations of the Food Safety Law

The Implementing Regulations of the Food Safety Law (Draft for Comments) was issued on 19 October and closed for public comments on 19 November. This Draft strengthens the administrative regime for special foods, i.e. healthcare foods, formula foods for special medical use, and infant formula foods. It also includes stricter requirements on labelling, instruction and advertisement; strengthening supervision and inspection of import food and implementing strictly legal liabilities for food manufacturers and traders.

The State Council issued the Outline of the Plan for Healthy China 2030

The State Council issued the Outline of the Plan for Healthy China 2030 ('Plan') on 25 October, which looks to build a healthy China by enhancing the innovation capability of patented drugs, new types of traditional Chinese medicines, new types of preparations, and advanced medical devices. The Plan encourages the launching of the generic drugs for the treatment of serious diseases and relevant patents that have been expired. It also encourages the development of biologics, new chemical drugs, and high performing medical devices.

CFDA establish Prior Approval for Medical Devices

CDFA published the Prior Review and Approval Procedure for Medical Devices ('Procedure') on 25 October, which was implemented on 1 January 2017. This Procedure lists several circumstances under which medical devices can enjoy prior approval, includes devices which have brought clinical advantages in diagnosing and treating orphan diseases, cancer and paediatric diseases; devices diagnosing and treating elderly endemic diseases and common diseases that have no effective diagnosing and/or treatment method; and devices of national major science and technology projects or key research and development programs; and other reasonable circumstances.

November

CFDA seeks public comments on the Adverse Events Monitoring and Re-evaluation of Medical Devices

The Administrative Measures for the Adverse Events Monitoring and Re-evaluation of Medical Devices (Draft for Comment) ('Draft'), published on 31 October was open for public comments until 30 November. According to the Draft, any serious adverse effects of medical devices shall be reported immediately to a system called 'National Monitoring Information Network for Adverse Events of Medical Devices'. For imported products and domestic products that are sold overseas, the manufacturers shall collect any serious adverse effects that occur overseas and report such events within 20 days.

Authorities issued the Planning Guidance of Pharmaceutical Industry Development

The CFDA and five other departments jointly published the Planning Guidance of Pharmaceutical Industry Development ('Guidance') on 9 November, which aims to improve the enforcement of anti-monopoly and anti-unfair competition laws, reinforce the IP protection regime, and enhance the supervision of counterfeit and false advertising. The Guidance mentions a market driven drug price formation mechanism and deeper reform to the review and approval system for drugs and medical devices.

Deepen the Reform on Medical and Health System

The Opinions on Further Promoting the Experience in Deepening the Medical and Health System Reform ('Opinions') were issued on 8 November. The Opinions state that the drug price mark-ups shall be cancelled in all public hospitals, and drug price negotiation regime will be applied to patented and exclusively manufactured drugs. A unified medical insurance system for urban and rural residents shall be established. Furthermore, non-public and public medical institutions will be treated equally in respect of market access, designated agencies for social insurance, technical access, etc.

Compilation Plan of Chinese Pharmacopoeia 2020 open for public comment

The Pharmacopoeia Commission of CFDA published the Compilation Plan of Chinese Pharmacopoeia 2020 (Draft for Comment) ('Draft') which closed for public comments on 1 December. The Draft offers guidance for the compilation work of the 2020 edition of Chinese Pharmacopoeia. It aims to increase the types of drugs covered by the Chinese Pharmacopoeia and remove drugs that do not meet current standards. A Drug's common clinical application, proven efficacy, safe usage, mature manufacturing process and controllable quality will be key considerations for inclusion on or removal from the list.

CFDA seek public comments on Administrative Measures for Drug Standards

The Administrative Measures for Drug Standards (Draft for Comment) ('Draft') was published on 22 November and is open for public comments until 20 January 2017. According to the Draft, the Drug Standards include National Drug Standards, Drug Registration Standards, Provincial Local Standards, Standard for Chinese Traditional Drug and Standard for Medical Institutions' Pharmaceutical Preparations. Technical requirements defined in the National Drug Standards would apply to all researchers, manufactures, operators, users and supervisors. Drugs which fail to satisfy the National Standards are prohibited from being manufacturing, distributing or being using. A six months' transitional period will apply after the National Standards issued.

December

CFDA seeks comments on the draft Good Clinical Practice

The Good Clinical Practice (Revision Draft for Comment) ('Draft') was published on 1 December 2016 and is open for public comments until 31 January 2017. The Draft is based on the international standard—ICH-E6 R2. The Draft stipulates stricter administration rules concerning the Institutional Review Board (IRB), investigators, sponsors, monitoring, the Contract Research Organisation (CRO), informed consent of the trial subject, trial protocol, investigator's brochure and document management. Moreover, the requirements for risk management of computerised system and data administration are formulated in the Draft for the first time.

MOFCOM issued the Development Plan of Drug Distribution Industry

The Ministry of Commerce ('MOFCOM') published the Development Plan of Drug Distribution Industry ('Plan') on 29 December. The Plan promotes the application of the internet and the Internet of Things (IOT) in the drug distribution sector. Foreign drug distributors are encouraged to expand their investment in China and participate in domestic M&A activities. The Plan also states that the relevant laws, regulations and policies will be refined gradually, especially the revision of Drug Administration Law.

CFDA issued the Guideline on GSP Onsite Investigation

The Guideline on Good Supply Practice Onsite investigation ('Guideline') was issued on 14 December 2016. According to the Guideline which follows the Good Supply Practice, drug distributors are required to establish a Drug Tracing System to ensure the traceability of drugs. This system replaces the Drug Electronic Monitoring Code. The distributors of In Vitro Diagnostic Reagents are also covered by this Guideline.

CFDA seek comments on Measures for the Inspection on Advertisements of Pharmaceutical Products

CFDA published Measures for the Advertisements Inspection on Drugs, Medical Devices, Healthcare Food and Formula Foods For Special Medical Use (Draft for Comment) ('Draft') on 14 December 2016 which is open for public comments until 13 January 2017. According to the Draft, advertisements for medical devices, healthcare foods and formula foods for special medical use will also subject to the drug administration regime. Internet advertisement shall be supervised according to the Draft. Administration on publishing drug advertisements in other places is released.

CFDA seek comments on Information Administration Regime

The Measures for Disclosure of Food and Drug Regulatory Information (Draft for Comment) ('Draft') was published on 15 December 2016 and is open for public comments until 13 January 2017. According to the Draft, regulatory information refers to the information formed and recorded in the administrative activities concerning food, drugs, medical devices and cosmetics such as product registration, manufacture and distribution licencing, advertisement inspection, sampling inspection, administrative penalty and so on. The regulatory information shall be published within seven working days after the completion of these relevant activities. An examination regarding confidential information contained in the regulatory information should be conducted before such information is disclosed.

Our top 10 predictions…

1. Drug Prices

High drug prices have been a widely criticised issue for many years. The Chinese government understands this is an important issue for citizens and is taking various direct and indirect measures to control prices. Since May 2015, a reform process has been underway which has included measures such as the implementation of the price negotiation regime in 2016. It is likely there will be further reforms in this area in 2017.

2. Anti-bribery

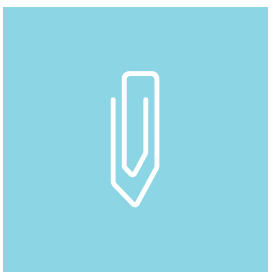
For many years, bribery in the Chinese medical industry has caused significant problems, including inflated drug prices and unnecessary treatments for patients. The government has tried various measures to solve this problem. In late December 2016, the official Central TV aired a special report on large scale bribery committed by pharmaceutical companies and doctors, which caused public outrage. The report indicates there may be another round of anti-bribery investigation in the medical industries in China.

3. Anti-trust

In 2016, the Chinese government significantly strengthened anti-trust investigatory powers in the lifesciences industry. Severe punishments have been handed down to both domestic and multinational companies for monopoly agreements regarding distribution or price, relating to drugs or medical devices. It is expected that anti-trust investigations will continue to be a powerful tool used by the government to control the price of medical product, and the wider market.

4. Registration regime

The pharmaceutical product registration regime was significantly altered in 2016 to include the new priority review channel, new classification for chemical drugs, and the pilot Market Authorisation Holder ('MAH') regime. It is said that the China Food and Drug Administration ('CFDA') will further reform the registration system to accelerate the review process, the MAH regime will be expanded and a patent linkage regime may also be established.



5. Administration

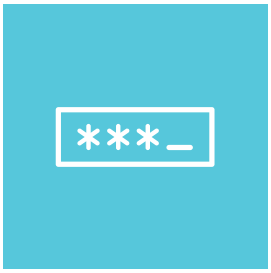
Last year, the CFDA tightened the administration measures relating to irregular registration, distribution and advertising of medical and food products. Several draft regulations on the safety assurance, adverse events monitoring and re-evaluation of medical and food products were also circulated, which may come into effect in 2017. It is expected that the CFDA will continue to pursue similar measures to ensure citizens safety and rights are protected.

6. Investment

The Chinese government has promised to improve the policy environment for social investment in the medical industry. Both private and public medical institutions will be treated equally in respect of market access, designated agencies for social insurance, and technical access. The social insurance companies are also encouraged to provide more medical insurance services and may be entrusted to handle part of their basic insurance affairs.

7. E-commerce

The internet and internet of things will be further promoted in the drug distribution industry. New e-medical services are also encouraged, which involve the cooperation of drug distributors, medical institutes and e-commerce enterprises, including online pharmacies and home delivery services for over-the-counter drugs. The more comprehensive regulatory regime contained in the Draft E-commerce Law will also facilitate the further development of e-commerce in this area.



8. Cybersecurity

The PRC Cybersecurity Law, which will take effect from 1 June 2017, will greatly influence M-health devices that collect information within China because of the information protection requirements contained in the new law. The CFDA has issued the Draft Technical Guiding Principles for the Cybersecurity Registration of Medical Devices which defines cybersecurity requirements during the registration of medical devices. Further regulations relevant to cybersecurity within the medical industry are expected to be issued once the new law comes into power.

9. Centralised distribution industry

The Ministry of Commerce, the competent authority in charge of M&A activities in China, considers the current industry structure unreasonable and further encourages M&A, IPOs and other activities between drug distributors. It is predicted that more intensive and informative large-scale distributing enterprises, covering the whole country, will be established.

10. Biotechnology

Developing biotechnology is an important part of the Chinese government's plan to enhance its innovation capabilities. According to the 13th Five-Year Plan for the Bio Industry, transitional medicine and precision medicine are encouraged to be further developed; biosimilar drugs like the monoclonal antibody, and the long-acting recombinant protein are to be developed. It is predicted that by 2020, the annual output value of bio industry shall be RMB 600 billion.

Need help getting ready for **the new Cybersecurity Law** in China on 1 June 2017?

Taking effect from 1 June 2017, the Cybersecurity Law will impact both domestic and foreign network operators and online service providers in China.

If your organisation engages in any of the following activities, you will need to consider the relevant requirements to be compliant:

— operation or administration of networks;
— provision of online services;
— supply or use of devices and equipment in networks;
— collection, processing or use of personal data;
— operation of 'critical information infrastructure';
— distribution of content through networks;
— use of networks in any other ways.

CMS can help you ensure you are compliant by conducting a Compliance Audit of your business. To find out more, please do contact us.

Nick Beckett
Managing Partner, Beijing Office
T +86 10 8527 0287
M +86 186 1842 8030
E nick.beckett@cms-cmck.com

Amanda Ge
Associate
T +86 10 8590 0769
E amanda.ge@cms-cmck.com

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