LexGTDT《药品和医疗器械法律法规 2021 年版》

中国篇（上篇）

作者：胡晓华、龚建华团队

世界著名法律媒体 Law Business Research 旗下 Lexology Getting The Deal Through 出版了《药品和医疗器械法律法规 2021 年版》中国篇（PHARMA & MEDICAL DEVICE REGULATION 2021）。北京天达共和律师事务所作为中国大陆地区唯一受邀参与撰写该书的律所，其医药及医疗健康团队近期完成中国篇供稿，中英文对照版如下：

医疗服务基本架构和主管机关

医疗保健相关的机构

1. 简要说明提供医疗服务和治疗产品的机构（公立和私营）及其职责。

Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

用于治疗的产品可以分为药品及医疗器械两大类。

药品上市许可持有人（MAH）对药品研制、生产、经营、使用全过程中药品的安全性、有效性和质量可控性负责。

MAH、药品生产企业及/或药品经销企业，应当依法取得药品上市、生产及销售相关许可。 医疗器械生产企业及/或医疗器械经销企业，应依据生产或经销的医疗器械类别，办理相关医疗器械生产及/或医疗器械经营备案或许可证。

医疗机构应依法取得医疗机构执业许可证，依照《药品管理法》有关规定使用药品、配置制剂。

药品行业协会、医疗器械行业协会主要负责建立健全行业规范，开展行

业发展问题的调查研究，参与行业标准的制定，组织技术交流与合作等工作。

Products for treatment in China can mainly be divided into drugs and medical devices.

The marketing authorisation holder (MAH) is responsible for the safety, efficacy and quality control of the drug throughout its development, production, distribution and use.

The MAH, manufacturer and distributor for a drug must obtain a business licence for marketing, manufacturing or distribution. The manufacturer or distributor for a medical device must obtain a licence or complete a record filing procedure for manufacturing or distribution that corresponds to the category and classification of the product.

Medical institutions must hold a licence for practice and use drugs and preparations in compliance with the Drug Administration Law.

The Pharmaceutical Industry Association and the Medical Device Industry Association are mainly responsible for establishing and improving industry norms, participating in the formulation of industry standards, organising technical exchanges and cooperation, etc.

主管机关

2. 说明负责批准医药产品和医疗器械上市的主管机关。按照什么样的规则来确定一个产品属于药品、医疗器械还是其他受管制类别（如化妆品或保健食品）？

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

国家药品监督管理局（NMPA）药品审评中心主管药品上市审批工作。就药品的上市审批而言，具体涉及到如下机构：受理服务中心、药品审评中心（CDE，负责临床和上市的技术审评）、食品药品检定研究院（负责样品检验和质量标准）、药品审核查验中心（负责现场核查）等。这些机构都是 NMPA 的直属机构。

医疗器械按照风险高低实行分类管理，对市场准入分别实行注册或备案管理。（i）第一类医疗器械实行产品备案管理，由备案人所在地设区的市级人民政府食品药品监督管理部门负责备案；（ii）第二类、第三类医疗器械产品，实行产品注册管理。其中第二类医疗器械由注册申请人所在地省、自治区、直辖市人民政府食品药品监督管理部门负责注册，第三类医疗器械由 NMPA 负责注册。

《药品管理法》《保健食品管理办法》《食品安全法》《保健食品检验与评价技术规范》《化妆品监督管理条例》，分别对药品、保健食品、食品、化妆品进行了定义和分类。

The National Medical Products Administration (NMPA) is in charge of drug marketing approval. The following institutions are involved in the approval process: the Centre for Acceptance and Service, the Centre for Drug Evaluation (CDE) (for clinical and marketing technical review), the Institute for Food and Drug Control (for sample testing and quality standards) and the Centre for Drug Inspection (for on-site inspection), among others. These institutions are all directly affiliated to the NMPA.

Medical devices are classified according to their risk level, which determines the form of their market access, registration or record-filing. Class I products are subject to record filing and should be filed with the food and drug administration of the local municipal government above the district level. Class II and Class III

products are subject to registration. Class II products should be registered by the provincial level local food and drug administration

where the applicant resides. Class III products should be registered by the NMPA.

Definitions and classifications of drugs, health food, food and cosmetics can be found in the Drug Administration Law, the Measures for the Administration of Health Food, the Food Safety Law, the Technical Specifications for Health Food Inspection and Evaluation and the Regulations on the Supervision and Administration of Cosmetics.

审批框架

3. 批准药品和医疗器械上市的一般法律和监管框架。

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

药品上市审批实行分类管理。药物注册分为中药、化学药和生物制品三大类，主要从药物的安全性、有效性和质量可控性以及申请人的质量管理、风险防控和责任赔偿能力等方面进行审查。

申请人在完成药学、药理毒理学和药物临床试验等研究，确定质量标准，完成商业规模生产工艺验证，并做好接受药品注册核查检验的准备后，提出药品上市许可申请，按照申报资料要求提交相关研究资料。

CDE 组织药学、医学和其他技术人员，按要求进行审评。审评结论通过的，批准药品上市，发给药品注册证书。

经核准的药品生产工艺、质量标准、说明书和标签作为药品注册证书的附件一并发给申请人，必要时还应当附药品上市后研究要求。

医疗器械的备案和注册应当提交下列资料：

（一）产品风险分析资料；

（二）产品技术要求；

（三）产品检验报告；

（四）临床评价资料；

（五）产品说明书及标签样稿；

（六）与产品研制、生产有关的质量管理体系文件；

（七）证明产品安全、有效所需的其他资料。

Classification-based management is carried out with regard to drug marketing approval. Drug registration is divided into three categories (traditional Chinese medicine, chemical drugs and biological products), and the review is conducted in consideration of the safety, efficacy and quality control of the drugs, as well as the applicant’ s quality management, risk prevention and control, and liability compensation capability.

The applicant completes research concerning pharmacology, pharmacotoxicology and drug clinical trials and then determines the quality standards, completes the commercial-scale production process validation and prepares to receive the inspection and verification of drug registration. The applicant then submits the drug marketing application accompanied by relevant research materials in accordance with the application requirements.

The CDE then organises pharmacological, medical and other technical personnel to conduct reviews in accordance with the requirements. If the review conclusion is passed, the drug is approved for marketing, and a drug registration certificate is issued.

The approved manufacturing process, quality standards, instruction sheet and labels are issued to the applicant as appendices of the drug registration certificate, together with the requirements for post-marketing studies, if necessary.

The following materials must be submitted for the record filing and registration of medical devices:

- product risk analysis information;

- product technical requirements;
- product inspection reports;
- clinical evaluation information;
- the instruction sheet and label samples;
- quality management system documents related to product development and production; and
- other information necessary to demonstrate the safety and effectiveness of the product.

临床试验

适用规则

4. 中国的医药产品和医疗器械临床试验的伦理委员会审批和执行受哪些法律规范，适用哪些规则?

   What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

药 品

相关适用法律法规主要包括如下：

- 中华人民共和国民法典
- 中华人民共和国药品管理法

药品注册管理办法

- 医疗机构制剂注册管理办法
- 药物临床试验质量管理规范
- 药品临床试验管理规范（试行），及

- 国际多中心药物临床试验指南（试行）

上述法规规定的有关适用原则如下：

- 为研制新药、医疗器械或者发展新的预防和治疗方法，需要开展药物临床试验，应当符合伦理原则，制定临床试验方案，经伦理委员会审查同意。
- 医疗机构制剂的临床研究，应当在获得《医疗机构制剂临床研究批件》后，取得受试者知情同意书以及伦理委员会的同意。
- 国际多中心药物临床试验，申办者应保证在获得伦理委员会的审查批准后才开始临床试验的实施。申办者和研究者要按照国际通行的 GCP 原则和伦理委员会的要求，向伦理委员会递交国际多中心临床试验进展情况。

医疗器械

相关适用法律法规主要包括如下：

- 中华人民共和国民法典
- 医疗器械临床试验质量管理规范
- 医疗器械拓展性临床试验管理规定（试行）

上述法规规定的有关适用原则如下：

- 医疗器械临床试验应当获得医疗器械临床试验机构伦理委员会的同意。
- 在临床试验过程中发生严重不良事件、影响受试者权益、安全和健康等情况时，应报告伦理委员会。
- 伦理委员会应当对本临床试验机构的临床试验进行跟踪监督，发现受试者权益不能得到保障等情形，可以在任何时间书面要求暂停或者终止该项临床试验。

Drugs

The main applicable legislation includes:

- the Civil Code;
- the Drug Administration Law;
- the Measures for the Administration of Drug Registration;
- the Administrative Measures for the Registration of Pharmaceutical Preparations of Medical Institutions;
- the Quality Management Norms for Drug Clinical Trials;
- the Drug Clinical Trial Management Norms (for Trial Implementation); and
- the Guidelines for International Multi-centre Drug Clinical Trial (for Trial Implementation).

The relevant rules from the above legislation are as follows.

- Drug clinical trials conducted to develop new drugs, medical devices or new prevention and treatment methods, should comply with ethical principles. The clinical trial plan must be approved by the ethics committee.
- With regard to clinical research of preparations in medical institutions, the medical institution must acquire the appropriate form of approval and obtain informed consent from the participant and the ethics committee.
- For international multicentre drug clinical trials, the sponsor must ensure that the clinical trial is conducted only after obtaining approval from the ethics committee. The sponsor and the researcher must submit updates on the trial to the ethics committee in accordance with the internationally accepted good clinical practice principles and the requirements of the ethics committee.

Medical devices

The main applicable legislation includes the Quality Management Norms for the Clinical Trials of Medical Devices and the Provisions on the Administration of Extended Clinical Trials of Medical Devices (for Trial Implementation). The relevant rules are as follows:

- medical device clinical trials should be approved by the ethics committee of the medical device clinical trial institution;
- serious adverse events occurring during clinical trials that affect the rights, safety and health, etc, of the participants must be reported to the ethics committee; and
- the ethics committee should follow up and supervise the clinical trials, and it may demand, in writing, the suspension or termination of the clinical trial at any time if it finds that the rights and interests of the participants cannot be protected.

报告要求

5. 对向主管机关或公众报告临床试验的开始及其结果有何要求?

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

药物临床试验应当经 NMPA 审查批准。NMPA 应当自受理临床试验申请之日起六十个工作日内决定是否同意，逾期未通知的，视为同意。

申办者应当在开展药物临床试验前在药物临床试验登记与信息公示平台登记药物临床试验方案等信息。药物临床试验期间，申办者应当持续更新登记信息，包括每年一次的安全性报告，在药物临床试验结束后登记药物临床试验结果等信息。登记信息在平台进行公示，申办者对药物临床试验登记信息的真实性负责。

药物临床试验登记和信息公示的具体要求，可以参考 2020 年 7 月 1 日

开始实行的《药物临床试验登记与信息公示管理规范（试行）》。

Drug clinical trials should be reviewed and approved by the National Medical Products Administration (NMPA). The NMPA shall decide whether to approve or disapprove the clinical trial application within 60 working days of the date of receipt of the application. If no notice is given after that date, approval is deemed to have been granted.

Before launching the drug clinical trial, the sponsor registers the trial plan and related information on the platform for drug clinical trial registration and information disclosure. During the trial, the sponsor must continuously update the registration information, including the annual safety report, and register the results after the trial is completed. The registration information is made public on the platform, and the sponsor is responsible for the authenticity of the information.

The Administrative Regulations for Drug Clinical Trial Registration and Information Disclosure (Trial), which came into effect on 1 July 2020, contains the specific requirements concerning registration and information disclosure of drug clinical trials.

同意和保险

6. 是否有获得试验受试者同意参与的强制性规定？申办者是否必须安排特定限额的人身伤害保险？

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

《中华人民共和国药品管理法》《药品注册管理办法》《药物临床试验质量管理规范》等法律法规中均规定，实施药物临床试验，应当向受试者或者

其监护人如实说明和解释临床试验的目的和风险等详细情况，取得受试者或者其监护人自愿签署的知情同意书，并采取有效措施保护受试者合法权益。

现有法律法规并未强制要求临床试验的申办者必须安排人身伤害保险，但《药物临床试验质量管理规范》要求临床试验的申办者应当承担受试者与临床试验相关的损害或者死亡的诊疗费用，以及相应的补偿。申办者和研究者应当及时兑付给予受试者的补偿或者赔偿。

Laws and regulations, such as Drug Administration Law, the Measures for the Administration of Drug Registration and the Quality Management Norms for Drug Clinical Trials, stipulate that, when conducting a drug clinical trial, the participant or his or her guardian must be given truthful explanations of the purpose, risks and other details of the clinical trial. Informed consent must be obtained from the participant or his or her guardian voluntarily. Effective measures must be taken to protect the legitimate rights and interests of the participant.

Existing laws and regulations do not compel the sponsor of a clinical trial to arrange personal injury insurance, but the Quality Management Norms for Drug Clinical Trials requires that the sponsor should bear the costs of treatment of the participant' s trial-related injuries or death, as well as the corresponding compensation. The sponsor and the researcher must pay compensation to the participant in due time.

上市许可

时间框架

7. 从申请到获得批准一般需要多长时间，需要支付哪些费用，以及批准的正常有效期是多久？

How long does it take, in general, to obtain an authorisation from

application to grant, what fees are payable and what is the normal period of validity of the authorisation?

根据《药品注册管理办法》规定，药品上市许可申请获得批准时限一般在二百二十五日以内。根据《医疗器械监督管理条例》规定，医疗器械注册获得批准的期限一般在二十三日以内，实践中一般需要 3 个月左右。

对药物临床试验申请、药品上市许可申请分别收取注册费用。新药（含各种类别的生物制品）与化学仿制药的收费标准存在不同。

对于医疗器械注册申请分别按照首次注册、变更注册、延续注册收取注册费用，各类费用收费标准存在不同。

药品注册证书及医疗器械注册证的有效期均为五年，持有人在有效期届满 6 个月可申请再注册或延续注册。

According to the Measures for the Administration of Drug Registration, the time limit for a drug marketing authorisation review is 200 days, and in practice it might be longer. According to the Regulations on the Supervision and Administration of Medical Devices, the period for obtaining approval for medical device registration is generally within 23 days, and in practice it generally takes around three months.

Registration fees are charged separately for drug clinical trial applications and drug marketing authorisation applications. The fees are different for new drugs and chemical generic drugs.

In the case of medical device registration applications, registration fees are different for the initial registration, change of registration and renewal of registration.

Both the drug registration certificate and the medical device registration certificate are valid for five years. The holder can apply for re-registration or renewal of registration six months before expiry.

对研究数据保护

8. 对于原研厂在首次申请，以及基于增加适应症或者改良剂型所提交的申请中的数据，可以获得何种保护或者市场独占权?

What protection or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

国家对获得生产或者销售含有新型化学成份药品许可的生产者或者销售者提交的自行取得且未披露的试验数据和其他数据实施保护，任何人不得对该未披露的试验数据和其他数据进行不正当的商业利用。6 年内，对其他申请人未经已获得许可的申请人同意，使用前款数据申请生产、销售新型化学成份药品许可的，药品监督管理部门不予许可。需要说明的是，药品试验数据保护期并非市场独占期，对提交自行取得数据的申请，NMPA 并不排斥。

2018 年 4 月 26 日，国家药品监督管理局公布了《药品试验数据保护实施办法（暂行）（征求意见稿）》，拓展了创新药和专用药比如孤儿药、儿童药等的数据保护，并首次提出了数据保护的申请、审查、授权公示、异议、撤销等机制。

China protects the undisclosed test data and other data submitted by manufacturers or distributors who have obtained licences to produce or sell drugs containing new chemical ingredients. No one can make improper commercial use of such undisclosed test data and other data. Within six years, if other applicants use the aforementioned data to apply for a licence to produce or sell the same or similar drugs without the consent of the approved applicant, the National Medical Products Administration (NMPA) will not grant the authorisation. The data protection provided does not equate to market exclusivity, and the NMPA does not exclude applications based on self-acquired data.

On 26 April 2018, the NMPA announced the Implementation Measures for the Protection of Drug Test Data (Interim) (Exposure

Draft), which expands the data protection of innovative drugs and special drugs, such as orphan drugs and children' s drugs, and proposes mechanisms for application, review, authorised publicity, objection and revocation of data protection.

信息自由

9. 第三方在多大程度上和何时可以申请获得申请人为获得药品和医疗器械上市批准所提交数据的副本?

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

就药品而言，NMPA 向社会公开批准上市药品的审评结论和依据，主要公开信息为药品受理号、受理日期、药品名称、类型、药品说明书及药品上市技术评审报告，公布时间根据具体情况有所不同，一般自药品监督管理局药品评审中心承办之日起 1 年至 2 年内公布，但不会公布申请人为获得药品上市批准提交的数据副本，目前也未规定第三方可通过申请获得相关数据。

就医疗器械而言，药品监督管理部门通过信息平台公布医疗器械许可、备案、抽查检验、违法行为查处情况等日常监督管理信息，但不会公布申请人为获得医疗器械上市批准提交的数据副本，目前也未规定第三方可通过申请获得相关数据。

With regard to drugs, the NMPA makes public the conclusion and basis for the evaluation of drugs approved for marketing. The main published information includes the acceptance number, acceptance date, drug name, type, instruction sheet and drug marketing technical review report. The publication time varies depending on the specific circumstances but is generally within one to two years of the acceptance date of the Centre for Drug Evaluation (CDE). However, the data submitted by the applicant will not be published, and there is no provision regarding third parties' applications to obtain a copy

of that data.

As for medical devices, the drug regulatory authority publishes, through the information platform, daily supervision and management information, but does not publish copies of data submitted by applicants for marketing approval. There is no provision regarding third parties' applications to obtain relevant data.

对特殊医药产品的监管

10. 对于某些类型的医药产品，如传统草药和顺势疗法产品、生物制剂和生物仿制药、受管制药品、孤儿药和儿科用药，是否有特殊的审批规则，以及对审批的奖励或激励措施?

Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

为鼓励药品创新，《药品注册管理办法》对基于不同情形而需要加快上市进程的药物设置了突破性治疗药物程序、附条件批准程序、优先审评审批程序和特别审批程序四个加快上市通道，对于符合条件的药物按规定给予药品审评中心交流指导，上市后提交补充申请和缩短审评时限等不同的政策支持。具体如下：

- 突破性治疗药物程序：药物临床试验期间，用于防治严重危及生命或者严重影响生存质量的疾病，且尚无有效防治手段或者与现有治疗手段相比有足够证据表明具有明显临床优势的创新药或者改良型新药等，可以申请适用突破性治疗药物程序。申请人可以享受在药物临床试验的关键阶段向药品审评中心提出沟通交流申请、将阶段性研究资料提交药品审评中心征求下一步研究方案的意见或者建议、以及申请适用优先审评审批程序等政策支持。
- 附条件批准程序：药物临床试验期间，符合以下情形的药品，可以

申请附条件批准：1）治疗严重危及生命且尚无有效治疗手段的疾病的药品，药物临床试验已有数据证实疗效并能预测其临床价值的；2）公共卫生方面急需的药品，药物临床试验已有数据显示疗效并能预测其临床价值的；3）应对重大突发公共卫生事件急需的疫苗或者国家卫生健康委员会认定急需的其他疫苗，经评估获益大于风险的。申请人可以享受药品上市后继续完成研究工作等政策支持。

- 优先审评审批程序：药品上市许可申请时，以下具有明显临床价值的药品，可以申请适用优先审评审批程序：1）临床急需的短缺药品、防治重大传染病和罕见病等疾病的创新药和改良型新药；2）符合儿童生理特征的儿童用药品新品种、剂型和规格；3）疾病预防、控制急需的疫苗和创新疫苗；4）纳入突破性治疗药物程序的药品；5）符合附条件批准的药品；6）国家药品监督管理局规定其他优先审评审批的情形。申请人可以享受缩短审评时限、优先安排核查、检验和核准药品通用名称等政策支持。
- 特别审批程序：在发生突发公共卫生事件的威胁时以及突发公共卫生事件发生后，国家药品监督管理局可以依法决定对突发公共卫生事件应急所需防治药品实行特别审批。申请人可以享受缩短审评时限等政策支持。

To encourage drug innovation, the Measures for the Administration of Drug Registration has set up four time-saving procedures to meet the needs under different circumstances: breakthrough therapeutic drug procedures, conditional approval procedures, priority review and approval procedures, and special approval procedures. The policy support offered by these procedures to eligible drugs includes communication with and guidance from the drug review centre, submission of supplementary applications after marketing and shortening of the review time frame.

Breakthrough therapeutic drug procedure

This concerns drugs in clinical trials that are used to prevent and treat a disease that severely threatens life or affects quality of life. While there is no other effective means of prevention or treatment, or there is sufficient evidence of significant clinical advantages over existing treatment methods, the breakthrough therapeutic drug procedure may be applied. Applicants can enjoy policy support such as requesting for communication and exchanges with the CDE during the clinical trial, soliciting comments or suggestions on the next stage of research after submitting phased research materials to the CDE, and applying for priority review and approval procedures.

Conditional approval procedure

Drugs in clinical trials that meet the following conditions are eligible to seek conditional approval:

- drugs used to treat severely life-threatening diseases with no effective treatments, of which the efficacy and clinical value can be validated by clinical trial data;
- drugs urgently needed for public health, of which the efficacy and clinical value can be shown and predicted by clinical trial data; and
- vaccines urgently needed in response to major public health emergencies or other vaccines identified by the National Health Commission as urgently needed, where the benefits are assessed to outweigh the risks.

Applicants may enjoy policy support such as continuing to complete the research after the drug is marketed.

Priority review and approval procedure

The following drugs with obvious clinical value may undergo the priority review and approval procedure:

- urgently needed clinical drugs in shortage, innovative drugs and

improved new drugs used to prevent and treat major infectious diseases and rare diseases;

- new paediatric drugs that meet the physiological characteristics of children;
- vaccines urgently needed for disease prevention and control and innovative vaccines;
- drugs included in the breakthrough therapeutic drug procedure;
- drugs included in the conditional approval procedure; and
- drugs under other circumstances specified by the NMPA for priority review and approval.

Applicants can enjoy policy support such as shortening of the review time frame, priority arrangement for verification, testing and approval of common names of drugs.

Special approval procedure

In the event of the threat of a public health emergency and after the occurrence of a public health emergency, the NMPA may decide in accordance with the law to apply the special approval procedure to the drugs required for handling the emergency. Applicants can enjoy policy support such as shortening of the review time frame.

药品上市后的安全监测

11. 产品上市后，相关授权的持有人有哪些药物警戒或器械警戒义务?

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

就药品而言，药品上市许可持有人需履行如下药物警戒义务：

- 对药品的非临床研究、临床试验、生产经营、上市后研究、不良反应监测及报告与处理等承担责任。
- 应当制定药品上市后风险管理计划，主动开展药品上市后研究，对药品的安全性、有效性和质量可控性进行进一步确证，加强对已上市药品的持续管理。
- 应当开展药品上市后不良反应监测，主动收集、跟踪分析疑似药品不良反应信息，对已识别风险的药品及时采取风险控制措施。
- 药品如存在质量问题或者其他安全隐患时，应立即停止销售，告知相关药品经营企业和医疗机构停止销售和使用，召回已销售的药品，及时公开召回信息，必要时应当立即停止生产，并将药品召回和处理情况向有关主管部门报告。

就医疗器械而言，医疗器械生产及经销企业需履行如下医疗器械警戒义务：

- 应当对所生产及经销的医疗器械开展不良事件监测；发现医疗器械不良事件或者可疑不良事件，应当向医疗器械不良事件监测技术机构报告。
- 当发现医疗器械不符合强制性标准、经注册或者备案的产品技术要求或者存在其他缺陷时，应当立即停止生产，通知相关生产及经销企业、使用单位和消费者停止销售和使用，必要时召回已经上市销售的医疗器械，采取补救、销毁等措施，记录相关情况，发布相关信息，并将医疗器械召回和处理情况向有关主管部门报告。

In the case of drugs, marketing authorisation holders (MAHs) have the following pharmacovigilance obligations:

- taking responsibility for the drugs' non-clinical research, clinical trials, production and distribution, post-marketing research, monitoring, reporting and handling of adverse reactions;
- formulating a post-marketing risk management plan, taking the initiative to conduct post-marketing studies, further validating the safety, efficacy and quality control of drugs, and strengthening the continuous

management of the marketed drugs;

- conducting post-marketing adverse reaction monitoring, actively collecting, tracking and analysing information on suspected adverse reactions, and taking risk control measures for drugs with identified risks in a timely manner; and

- stopping the sale of drugs immediately if there are quality problems or other safety hazards, notifying relevant drug distributors and medical institutions to stop sales and use, recalling the drugs that have been sold, and disclosing recall information in a timely manner, as well as, if necessary, stopping production immediately and reporting to the relevant authorities the situation of the recall and disposal of the drugs.

In the case of medical devices, the manufacturer and distributor have the following vigilance obligations:

- carrying out adverse event monitoring, and reporting adverse events or suspicious adverse events to the government agency; and

- immediately stopping production, notifying the relevant manufacturers and distributors, users and consumers to stop sales and use, if necessary recalling medical devices on the market, taking remedial and destruction measures, recording the relevant situation, releasing relevant information, and reporting the recall and handling of the medical devices to relevant authorities upon discovering that the product does not meet the mandatory standards, the technical requirements concerned or other defects.

其他许可

12. 制造、进口、出口或进行医药产品和医疗器械的批发分销和储存需要哪些许可？申请时需要向当局提供什么类型的信息，费用是多少，以及通常的有效期是多久？

What authorisations are required to manufacture, import, export or

conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

就药品而言，药品生产须取得药品生产许可证（有效期为 5 年），申请时需提供药学技术人员、工程技术人员，法定代表人、生产管理负责人、质量管理负责人等有关人员情况，厂房、设施、设备和卫生环境情况，规章制度情况等；药品批发、零售需取得药品经营许可证（有效期为 5 年），申请时需提供的信息与前述药品生产许可证申请所需信息相似。

进口药品，应当按照国务院药品监督管理部门的规定申请注册。国外企业生产的药品取得《进口药品注册证》后，方可进口。

进口药品到岸后，进口药品的企业应向口岸所在地药品监督管理部门备案，海关凭药品监督管理部门出具的进口药品通关单办理通关手续。药品出口应办理药品出口销售证明。

医疗器械生产许可证、经营许可证有效期均为 5 年

前述办理有关许可的费用无统一标准，不同地区收取的费用存在不同。

In the case of drugs, the production of drugs requires a drug manufacturing certificate (valid for five years), the application for which requires the information of relevant personnel, such as the pharmaceutical technicians, engineering and technical personnel, as well as the conditions of the plant, facilities, equipment and sanitary environment, etc. The wholesale and retail sale of drugs requires a drug supply certificate (valid for five years), the application of which requires information similar to that for a drug manufacturing certificate.

Imported drugs must apply for registration in accordance with the NMPA regulations. For drugs produced abroad, the imported drug registration certificate is required before importation. After the imported drugs arrive at the port, the importing drug company must

make a filing with the drug regulatory authority at the port location, and customs handles the customs clearance procedures. For drug export, an application for a drug export sales certificate is required

In respect of medical devices, the medical device production licence and the distribution licence are both valid for five years.

There is no uniform fee schedule for the aforementioned permits; different fees are charged in different regions.

制裁措施

13. 当局对违反有关受控活动的规定的实体或其董事和高级职员可实施哪些民事、行政或刑事制裁?

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

药品监督管理部门对违反规定的药品、医疗器械的生产、经营者可采取下列行政处罚措施:

- 警告;
- 没收违法所得;
- 没收违法生产、销售的药品、医疗器械和用于违法生产经营的工具、设备、原材料等物品;
- 责令停产停业;
- 罚款;
- 吊销生产许可证或者经营许可证;
- 违法情节严重的，可对法定代表人、主要负责人、直接负责的主管人员和其他责任人员没收违法行为发生期间自本单位所获收入，处以罚款、终身或一定期限内禁止从生产经营活动、拘留等行政处罚。

构成生产、销售不符合标准的医用器材罪或假药、劣药罪的，可能处以有期

徒刑、无期徒刑、死刑、拘役，并处罚金或者没收财产等刑事处罚。造成人身、财产或者其他损害的，相关责任主体（MAH、生产商或医疗机构）将依法承担民事赔偿责任。

The drug regulatory authority may impose the following administrative penalties on the manufacturer and distributor or their directors and officers for breach of the relevant regulations:

- a warning;
- confiscation of illegal income;
- confiscation of drugs and medical devices illegally produced and sold, as well as tools, equipment, raw materials, etc, used in illegal production and distribution;
- an order to suspend production and distribution;
- fines;
- revocation of the production or distribution licence; or
- if the violation is serious, the legal representative, the principle person in charge, the directly responsible person and other responsible persons may be subject to administrative penalties, such as confiscation of the income obtained from the company during the period of the violation, fines, prohibition from production and distribution for life or for a certain period of time, and detention.

If the acts constitute the crime of producing or selling medical equipment that does not meet the requisite standards or the crime of producing or selling counterfeit or inferior drugs, the defendant may be sentenced to fixed-term imprisonment, life imprisonment, the death penalty, criminal detention, fines or confiscation of property.

Where any harm is caused by defective drugs or medical devices, the patient may claim civil compensation from the responsible party (eg, the MAH, manufacturer or medical institution).

豁免

14. 药品生产和供应中有哪些可以免除获得上市许可的要求（例如，药剂师为某位特定患者配制药物）？

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

医疗机构经省级人民政府卫生行政部门和药品监督管理部门批准后可以设立制剂室，可以根据临床需要配制制剂（麻醉药品及生物制品制剂除外），但是以自用为原则，不得在市场进行销售。

Medical institutions may set up preparation laboratories upon approval by the health administration of the provincial government and the drug regulatory authority, and they may make preparations (except for narcotic drugs and biological preparations) according to clinical needs. However, these preparations can only be prescribed by the medical institutions themselves and are not allowed for sale.

平行貿易

15. 是否允许将已在另一司法管辖区获得授权的成品进口到贵国司法管辖区，而不需要进口商提供获得市场授权通常所需的全部细节。相关要求有哪些?

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide the full particulars normally required to obtain an authorisation to market? What are the requirements?

一般是不允许的。如果某药品已经在其他国家获得批准，则应该按照仿制药进行申报。这种情况下，审评工作主要着眼于人种差异和桥接试验。但是，仍然要按照《药品注册管理办法》等有关对药品的细化分类和相应的申报资料要求进行申报，由 CDE 对药品上市许可申请进行审评，综合审评结论通过的发给药品注册证书。

就医疗器械而言，向中国境内出口第一类医疗器械的境外生产企业，由其在中国境内设立的代表机构或者指定中国境内的企业法人作为代理人，根

据出口医疗器械的类别和分类，向药品监督管理部门提交备案或注册所需材料。

These imports are normally not allowed. If the drug is already authorised in another jurisdiction, it falls into the category of generic drugs, which means that the review would focus on ethnic sensitivity and bridge studies instead of a full clinical study. Nonetheless, the importer must apply for a marketing authorisation in accordance with the detailed classification of drugs and corresponding materials provided in the Measures for the Administration of Drug Registration and other related regulations. The CDE reviews the application and issues the drug registration certificate if the comprehensive review conclusion is passed.

In the case of medical devices, an overseas manufacturer exporting products to China must, through its representative office established in China or a corporate legal person designated in China as its agent, submit to the drug regulatory authority the filing or registration materials and the documents, as requested depending on the category and classification of the products.