# China Adopts Revised Drug Administration Law
# 中国颁布新修订版药品管理法

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On August 26, 2019, China's Standing Committee of National People's Congress ("NPC) adopted a significant revision of the Drug Administration Law ("DAL"). The newly adopted DAL ("Revised DAL") will go into effect on December 1, 2019. The Revised DAL is the first overhaul of the DAL since 2001.[1]
2019 年 8 月 26 日，中国全国人民代表大会常务委员会（"人大常委会"）通过了《药品管理法》的重大修订版。新通过的《药品管理法》（下称"修订版《药品管理法》"）将于 2019 年 12 月 1 日生效。修订版《药品管理法》是该法自 2001 年以来的首次大幅修订。[2]

Perhaps the most significant feature of the Revised DAL is the adoption of a nationwide marketing authorization holder ("MAH") system. This system links marketing licenses directly to the products, permitting flexibility in designing contract manufacturing and distribution arrangements. The Revised DAL addresses a number of other significant issues, including encouraging drug innovation, facilitating the drug approval process, improving drug traceability and pharmacovigilance, and amending the definition of counterfeit drugs. This client alert highlights and summarizes important takeaways of the Revised DAL.
修订版《药品管理法》最重要的特色或许即是在全国采纳上市许可持有人制度。该制度将上市许可与产品直接挂钩，允许对委托生产和经销安排进行灵活的设计。修订版《药品管理法》还涵盖了若干其他重要问题，包括鼓励药品创新、优化药品审批流程、健全药物追溯和药物警戒制度以及修订假药定义。本文将重点介绍并归纳修订版《药品管理法》的要点。

## Expansion of MAH System Nationwide
## 上市许可持有人制度扩展到全国

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The Revised DAL officially adopts the Pilot MAH Program ("Pilot Program") that began in 10 provinces and cities in 2015 and was extended through November 2019.[3] The Pilot Program allows domestic research institutions, drug manufacturers, and individuals to hold licenses to market drug products without holding a manufacturing license for a facility. Previously, the facility license requirement blocked research-based companies from bringing their drugs to market without partnering with a larger company. Companies abroad that manufacture imported drugs and hold imported drug licenses could not participate in the Pilot Program.
修订版《药品管理法》正式采纳了 2015 年在 10 个省市开展并延期至 2019 年 11 月的上市许可持有人制度试点方案（下称"试点方案"）。[4]试点方案允许国内研究机构、药品生产商和个人持有药品上市许可，而无需就药品生产设施持有生产许可证。之前，持有药品生产许可证的要求使研究性企业不得不和大公司合作，否则无法让其产品上市。并且，生产进口药品及持有进口药品许可的境外公司无法参与试点方案。

Under the Pilot Program, qualifying individuals or entities can either contract out to one or more contract manufacturers or distributors or hold their own manufacturing and distribution licenses for certain activities.[5] MAHs are permitted to sell their drugs directly to another distributor without having to apply for a drug distribution license, provided that they meet certain substantive criteria.
根据试点方案，具备资格的个人或实体可委托一个或多个受托生产企业或经营企业，或就特定活动持有自己的生产和经营许可。[6]只要其满足某些实质性标准，上市许可持有人可以直接向另一经销商出售其产品而无需申请药品经营许可。

Although the Revised DAL largely adopts the contours of the Pilot Program, there are a few notable differences in the Revised DAL:
尽管修订版《药品管理法》采纳了试点方案的大多数内容，但仍有一些值得注意的差异：

Perhaps most notably, in the Revised DAL a foreign entity can now be a MAH, provided that it designates an entity in China to perform the MAH's obligations.[7] The Revised DAL does not make it clear whether a domestic MAH may use foreign manufacturing sites, or vice versa. Under current practice, the manufacturing location dictates whether the drug product and the license holder is domestic or foreign. In other words, if the manufacturing location is in China, the license holder must be in China, and if the manufacturing location is outside of China, the license holder must be outside of China.
修订版《药品管理法》中最值得注意的或许即是，只要指定一家中国境内的企业法人履行上市许可持有人的义务，境外企业也能成为上市许可持有人。[8]修订版《药品管理法》未明确境内上市许可持有人是否可以使用外国生产场地或境外上市许可持有人是否可以使用中国生产场地。在目前的实践中，生产地点决定了药品和药品上市许可的持有人是境内的还是境外的。换言之，如果生产地点在中国，药品上市许可的持有人必须在中国，如果生产地点在境外，药品上市许可的持有人也必须在境外。

Although the scope of potential MAH applicants in the Revised DAL includes enterprises, research institutions, and "others,"[9] it is not clear whether "others" would still include individual researchers, as is the case in the Pilot Program. In fact, the State Council noted in a 2018 observation report regarding the Pilot Program that individual researchers might not be able to ensure the safety and quality of the products due to their limited capabilities, and there is no precedent in any of the 10 Pilot Program provinces that an individual researcher has successfully become an MAH.[10]
尽管修订版《药品管理法》中潜在上市许可申请人的范围包括企业、药品研制机构"等"。[11]这里的"等"是否如试点方案一样仍包括个人研究者尚不明确。事实上，国务院在 2018 年的一份关于试点方案的观察报告中指出，个人研究者可能因为其能力有限而无法确保产品的安全性和质量，而且在 10 个试点省市中均没有个人研究者成功成为上市许可持有人的先例。[12]

The Revised DAL sets forth a more concrete, consolidated list of MAH responsibilities. Together with establishing a stronger pharmacovigilance and post-market surveillance system (discussed below), the Revised DAL makes it clear that MAHs are responsible for the safety, efficacy, and quality of their drugs during the entire "life-cycle," including non-clinical research, clinical trials, manufacture, distribution, and post-marketing surveillance.
修订版《药品管理法》规定了更具体、全面的上市许可持有人责任范围。除了建立更强的药物警戒制度和上市后监测体系（见下文讨论）外，修订版《药品管理法》还明确，上市许可持有人对其产品全"生命周期"的安全性、有效性和质量负责，包括非临床研究、临床试验、生产经营及上市后监测。

Importantly, similar to the Pilot Program, the Revised DAL allows transfer of a product's marketing authorization, provided that the transferee has the capacity for quality control, risk management, and compensation for claims and to ensure the safety, efficacy, and quality of the product.[13] Details on how a transferee can demonstrate sufficient capacity in this regard are not clear.
重要的是，与试点方案类似，修订版《药品管理法》允许转让产品的上市许可，前提是受让方应当具备保障药品安全性、有效性和质量可控性的质量管理、风险防控和责任赔偿等能力。[14]关于受让方如何证明在此方面具备充分能力尚不明确。

## Encouragement of Innovation
## 鼓励创新

The newly adopted DAL codifies certain prior reform policy measures based on a 2017 policy document (the Innovation Opinion).[15] These include the following examples.
新通过的《药品管理法》将基于 2017 年一项政策文件（下称“创新意见”）的某些先前的改革政策措施确立为了法律。[16]例如：

### Priority Review
### 优先审评

The Revised DAL adopts China's existing commitment to encourage clinical value-oriented drug innovations,[17] stating that priority review and approval will be available for drugs for pediatric indications, urgently needed drugs for clinical use that are in short supply, new drugs for major contagious diseases, or drugs for orphan diseases.[18]
修订版《药品管理法》反映了中国支持以临床价值为导向的药物创新的既定承诺，[19]规定，对于儿童用药、临床急需的短缺药品、防治重大传染病或罕见病的新药给予优先审评审批。[20]

### Conditional Approval
### 附条件批准

The Revised DAL adopts a conditional approval pathway that had already been established by prior policy documents. Drugs that treat life-threatening illnesses for which there is no effective treatment, and drugs for which there is an urgent public health need, can be approved on the condition that studies are completed post-marketing if the drug's effectiveness has been demonstrated through early-stage clinical trial data.
修订版《药品管理法》采纳了先前政策文件已建立的附条件批准通道。对治疗严重危及生命且尚无有效治疗手段的疾病以及公共卫生方面急需的药品，如果药品的有效性已通过早期临床试验数据得到证明，在满足上市后完成研究的条件下药品可获得批准。

The MAH of a conditionally approved drug must undertake risk management measures in addition to completing required supplementary research in accordance with the conditions set forth in its marketing authorization. Failure to meet these conditions could result in the revocation of the drug license.
附条件批准药品的上市许可持有人必须采取风险管理措施，根据其上市许可中阐明的条件完成要求的补充研究。未满足这些条件可能导致药品上市许可被注销。

### Clinical Trial Implicit Approval and Bioequivalence Notification Systems
### 临床试验默示批准和生物等效性备案体系

The Revised DAL adopts an existing system that permits clinical trials to proceed in accordance with the submitted protocol if there is no objection from the National Medical Products Administration ("NMPA") within 60 working days of the date of filing the application. NMPA has been implementing this system for new drug trials since mid-2018. There is no limitation for "new" drug trials in the Revised DAL. Prior to this approach, NMPA's review and approval of a clinical trial application could take one year or longer. Separately, the Revised DAL also incorporates and confirms another existing NMPA rule that bioequivalence studies for generic drugs are subject to a different notification system.
修订版《药品管理法》采纳了现行体系，即自临床试验申请提交之日起 60 个工作日内若国家药品监督管理局（下称"国家药监局"）无异议，则允许临床试验根据已提交方案进行。国家药监局自 2018 年年中以来一直在实施该新药试验体系。修订版《药品管理法》中并未将这一规定仅限适用于"新"药试验。在采用此方法之前，国家药监局对临床试验申请的审批可能需要一年或更久。此外，修订版《药品管理法》还纳入并确认了另一项现行的国家药监局规定，即仿制药的生物等效性试验适用于一套不同的备案体系。

### Notification System for Clinical Trial Sites
### 临床试验机构的备案体系

Clinical trials can be conducted only at institutions that have been inspected and accredited by NMPA with departments that are certified for that type of clinical investigation. Under the Revised DAL, the accreditation process no longer requires pre-approval; notification is sufficient. This notification approach has been in effect since 2017 for clinical trial sites that carry out bioequivalence experiments of generic drugs.[21] Also, prior to the Revised DAL, the notification system had never been implemented for new drug trials of new drugs, even though several drafts containing this proposal were announced over the past two years.[22]
临床试验仅可在经国家药监局检查和认定的机构与具备该类临床研究资格的机构进行。根据修订版《药品管理法》，该认定程序不再需要事先批准；备案就足够了。该备案方法自 2017 年以来对进行仿制药生物一致性试验的临床试验场地有效。[23]另外，尽管过去两年里发布了包含此项建议的几个草案，在修订版《药品管理法》颁布之前，该备案体系从未对新药试验实施。[24]

## Simplified Definition of "Drug"
## 简化"药品"定义

The Revised DAL simplifies the definition of "drug" and removes active pharmaceutical ingredients ("APIs") from its scope.[25] Whereas the prior definition contained a long list of different types of medicines,[26] the new definition states that a drug falls into one of three categories only: "traditional Chinese medicines, chemical drugs and biological products." Classification of a product as a "drug" continues to be based on whether it is used to prevent, treat, or diagnose human illness with a purpose of regulating human physiological functions with designated indications or primary treatment functions, a use method, and dosage.
修订版《药品管理法》简化了"药品"的定义，从其范围中删除了原料药。[27]虽然之前的定义包含一份很长的不同类型药品的清单，[28]新定义称，药品仅分为三类："中药、化学药和生物制品"。将产品归类为"药品"仍然取决于其是否用于预防、治疗、诊断人的疾病，有目的地调节人的生理机能并规定有适应症或者功能主治、用法和用量。

The removal of APIs from the definition leaves unclear the applicability of other drug-related rules to APIs. A separate article of the Revised DAL states that the production of APIs must comply with Good Manufacturing Practice ("GMP") rules and applicable standards,[29] but it is not clear whether other drug-related rules would apply, such as Good Supply Practice ("GSP") or other distribution rules.
从定义中删除原料药使得其他药品相关规则对原料药的适用性变得不明确。修订版《药品管理法》专门有一条规定，原料药的生产必须符合药品生产质量管理规范（"GMP"）的要求及相关规范，[30]但其他药品相关规定（如药品经营质量管理规范（"GSP"）或其他经营规定）是否适用尚不明确。

The Revised DAL does not define the terms, "new drug," "innovative drug," or "generic drug."
修订版《药品管理法》未对"新药"、"创新药"或"仿制药"作出定义。

## Combined Review for API, Pharmaceutical Excipients, and Packaging
## 原料药、药用辅料和包装的合并审批

Approval of APIs, pharmaceutical excipients, and packaging materials will now be combined with the drug registration review process, instead of requiring applicants to submit separate applications.[31] The Revised DAL codifies the system that has been in place since November 30, 2017, when NMPA stopped accepting separate applications for APIs, excipients, and packaging, and began reviewing them together with the corresponding drug application.[32]
对原料药、药用辅料和包装材料的审批现在将与药品注册审批程序一并进行，而不要求申请人单独提交申请。[33]修订版《药品管理法》将自 2017 年 11 月 30 日以来实施的体系确立为法律，即国家药监局不再接受单独的原料药、药用辅料和包装申请，而开始将此类申请与相应的药品申请一并审评审批。[34]

## Abolition of Separate GMP and GSP Certificates
## 取消单独的 GMP 和 GSP 证书

The Revised DAL combines drug manufacturing and distribution licenses with GMP and GSP certificates. Thus, only a single process and inspection should be necessary to accredit a facility for manufacturing or distribution. Drug manufacturers and drug distributors must still comply with current GMP and GSP requirements. And, indeed, pursuant to the Revised DAL, NMPA and its provincial counterparts are directed to strengthen their surveillance of drug manufacturers and distributors, including through regular and continuous site inspections.
修订版《药品管理法》将药品生产经营许可与 GMP 和 GSP 证书予以合并。因此，应当只需要实施单一的程序和检查来认证生产或经营设施。药品生产企业和经营企业仍然必须遵守目前的 GMP 和 GSP 要求。实际上，根据修订版《药品管理法》，国家药监局及省级药监机构被要求加强对药品生产企业和经营企业的监管，包括定期和持续进行现场检查。

## Online Distribution of Drugs
## 药品的网络销售

The Revised DAL allows MAH and licensed drug distributors to sell drugs online, except for vaccines, blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, pharmaceutical precursor chemicals and other drugs under special state

administration.[35] Third-party online drug distribution platforms must complete a record filing process, and are required to check the qualifications of the distributor's license and manage the drug distribution that occurs on the platform.
修订版《药品管理法》允许上市许可持有人和被许可的药品经营企业在网络上销售药品，疫苗、血液制品、麻醉药品、精神药品、医疗用毒性药品、放射性药品、药品类易制毒化学品等国家实行特殊管理的药品除外。[36]药品网络交易第三方平台须进行备案，并应当对经营企业的资质进行审核，管理平台上的药品经营行为。

Unlike current rules and prior drafts of the DAL,[37] there is no prohibition on the distribution of prescription drugs. Although this apparent flexibility in the DAL is significant, it does not necessarily mean that online distribution of prescription drugs will be permitted, and the final direction will likely be determined by implementing regulations. According to senior NMPA officials, the NPC adopted an "inclusive and prudent attitude" during the revision of the DAL, and will listen to the opinions of relevant departments to further draft administration measures for online drug distribution.[38]
与目前的规定及之前版本的《药品管理法》不同的是，[39]处方药的销售未被禁止。尽管《药品管理法》中这一灵活规定意义重大，但并不一定意味着网络销售处方药将被允许，最后的方向很可能由实施细则确定。国家药监局高级官员表示，全国人大在修订《药品管理法》期间采取了"包容审慎的态度"，且会听取相关部门的意见，以进一步起草网络药品销售管理办法。[40]

## Improvement of the Drug Traceability System
## 药品追溯制度的改善

The DAL requires MAHs, drug manufacturers, drug distributors, and hospitals to implement a drug traceability system.[41] The purpose of this system is to ensure the traceability of a drug's entire life-cycle—from research through production and usage[42]—to eliminate counterfeit or substandard drugs, and to conduct recalls accurately.
《药品管理法》要求药品上市许可持有人、药品生产企业、药品经营企业和医疗机构实施药品追溯制度。[43]该制度的目的是确保药品全生命周期（从研制生产到使用）的可追溯性 [44]，以消灭假药劣药，及准确地执行召回。

This reform follows a number of prior efforts to improve the drug traceability system. Over the last year, NMPA has been working on a traceability system under which MAHs, drug manufacturers, drug distributors, and relevant medical institutions are required to keep records of their activities and provide traceability data to NMPA through an online platform, which will be publicly available.[45] MAHs and drug manufacturers are required to assign a unique traceability mark, generated in accordance with a uniform coding rules, to each product packaging unit.[46] It is not clear how the Revised DAL will affect the implementation of NMPA's system. It is likely that NMPA will release more rules to clarify each party's responsibilities and the timing for implementation.
此项改革遵循了之前改善药品追溯制度的若干措施。在去年，国家药监局一直在建设一项追溯制度，要求药品上市许可持有人、药品生产企业、药品经营企业及相关医疗机构保留其活动的记录，并通过一个在线平台向国家药监局提供追溯数据（这些数据将成为公开可获得数据）。[47]药品上市许可持有人及药品生产企业须为每个产品包装单元指派根据统一编码规则生成的，独一无二的的追溯码。[48]修订版《药品管理法》将对国家药监局的这一制度有何影响尚不明确。国家药监局很可能会发布更多规则，以明确各方的责任和实施时间。

## Pharmacovigilance System
## 药物警戒制度

The Revised DAL increases the requirements for pharmacovigilance, including requiring MAHs to create management plans, conduct post-marketing research to continually assess a drug product's safety and effective, and institute robust adverse event monitoring practices.[49]
修订版《药品管理法》增加了药物警戒要求，包括要求药品上市许可持有人制订管理计划，进行上市后研究，对药品的安全性、有效性进行进一步确证，以及实施有效的不良反应监测措施。[50]

Specifically, a MAH is required to proactively monitor, gather, and analyze adverse events. While MAHs are primarily responsible for this work, drug manufacturers, drug distributors, and medical institutions also must regularly consider adverse events related to the products they make, distribute, or use. If they discover a suspected adverse event, they must report it promptly to the authorities in charge of drug and health administration at local levels. The precise details of this reporting system will be addressed in implementing regulations. The Revised DAL is not clear on whether or how the seriousness of the adverse event will affect reportability.
具体而言，药品上市许可持有人需主动开展不良反应的监测、收集和分析。虽然药品上市许可持有人主要负责此项工作，但药品生产企业、药品经营企业及医疗机构也须定期考虑与其生产、经营或使用的药品相关的不良反应。如果发现可疑的不良反应，这些单位须及时向负责药品和卫生的地方政府部门报告。该报告制度的具体详情将在实施细则中规定。修订版《药品管理法》对于不良反应的严重程度对可报告性是否有影响或如何影响未作明确阐述。

If a marketed drug has quality or other safety issues, the MAH must cease distribution and/or manufacturing immediately and conduct a recall.[51] Consistent with existing practice, NMPA has the power to order a recall and stop distribution, even if the MAH does not choose to do so.[52]
如果已上市药品有质量或其他安全性问题，药品上市许可持有人须立即中止经营和/或生产，并执行召回。[53]根据现有实践，药品上市许可持有人依法应当召回药品而未召回的，国家药监局有权责令其召回和停止经营。[54]

The Revised DAL also creates a risk-based system for amending marketing authorizations, depending on the impact of the change on safety, effectiveness, and quality control. Significant changes require preapproval by NMPA, while lesser changes can be notified or included in periodic reports.
修订版《药品管理法》还建立了基于风险变更上市许可的制度，具体操作取决于变更对于安全性、有效性和质量控制的影响。重大变更需经国家药监局事先批准，而较小的变更可采取备案或加入定期报告的方法。

## Expanded Access Programs
## 拓展性临床试验

The Revised DAL creates an expanded access pathway for investigational drugs under which a company sponsor of a clinical trial in China can apply to establish an expanded access treatment program for patients with life-threatening illnesses that otherwise cannot qualify for a clinical trial.
修订版《药品管理法》为临床试验用药物的拓展性使用建立了通道，中国临床试验的公司申办人可申请为患有严重危及生命疾病，但不具备临床试验资格的患者建立拓展性临床试验治疗方案。

To quality for expanded access: (1) the drug must be used for life-threatening diseases that lack effective treatment; (2) the drug must have demonstrated its potential effectiveness based on medical observations; (3) such use is in line with ethical principles; (4) such expanded uses have been reviewed and approved (although the approval pathway not clear), and have obtained patients' informed consent; and (5) the drug must be used within the clinical trial institution and used on patients with similar conditions.[55] Unlike the prior draft of the DAL in April 2019, the Revised DAL does not require that expanded access patients be incorporated into the scope of the trial.
为获得拓展性临床试验的资格，药品需满足以下条件：(1)药品须用于治疗危及生命且尚无有效治疗手段的疾病；(2)药品须基于医学观察证明其具有潜在有效性；(3)药品的使用符合伦理原则；(4) 拓展性临床试验已获得审批（但审批通道不明确），且获得了患者的知情同意；和(5)药品须在开展临床试验的机构内使用，且可用于其他病情相同的患者。[56]与 2019 年 4 月的前一版《药品管理法》不同，修订版《药品管理法》未要求将拓展性临床试验中的患者纳入试验的范围。

## Special Importation of Unapproved Drugs
## 未经批准药品的特别进口

The Revised DAL grants provincial governments authority to approve the one-time importation of unregistered foreign drugs for urgent clinical use. Under the prior DAL, the authority to approve importation of unapproved drugs belonged to NMPA, but the agency has rarely invoked this authority to approve these requests. This change is similar to the measures adopted as part of a pilot program in Hainan Province in the Bo'ao Medical Tourism Zone (see our alert, here) under which the local affiliate of NMPA can approve special importation.
修订版《药品管理法》授权省级政府批准一次性进口未注册外国药品以满足临床急需。在之前的《药品管理法》中，批准进口未批准药品的权力属于国家药监局，但该机构很少行使批准此类申请的权限。此项变动类似于在海南省博鳌乐城国际医疗旅游先行区（请参阅我们的期刊）作为试点方案的一部分采纳的措施。根据该试点方案，省级人民政府可批准特殊的进口申请。

## Decreased Penalties for Importation of Unapproved Drugs
## 减轻对进口未经批准药品的处罚

The Revised DAL removes manufacturing and importation of unapproved drugs from the definition of counterfeit drugs, and it reduces or eliminates the penalty for importation of small amounts of these drugs. Under prior practice, drugs imported or manufactured without NMPA approval were deemed counterfeit drugs with stringent penalties, including fines and criminal liability.[57] The Revised DAL still explicitly prohibits importing unapproved drugs, but now states that authorities might reduce the penalty or impose no penalty for the importation of a small amount of a drug that has been legally marketed abroad. The relevant provision does not limit this potential mitigation to importation for personal use.[58] The change likely follows from significant public and media attention on efforts to import inexpensive generic drugs.
修订版《药品管理法》从假药定义中删除了未批准药品的生产和进口，并减轻或取消了对进口少量此类药品的处罚。根据之前的实践，未经国家药监局批准而进口或生产的药品被视为假药， 面临严厉的处罚，包括罚金和刑事责任。[59]修订版《药品管理法》仍然明确禁止进口未经批准的药品，但规定，对于进口少量境外已合法上市的药品，监管部门可减轻处罚或免予处罚。 相关条款并未称，此项减免处罚规定仅限于个人用途的进口。[60]该项变动很可能起因于公众和媒体对于进口便宜仿制药的努力的密切关注。

## Enhanced Penalties
## 加重处罚

Consistent with the trend in food and drug regulation in China over the last several years, the Revised DAL contains increased monetary and other penalties.
与中国过去几年里食品药品监管的趋势一致，修订版《药品管理法》包含加大的罚款金额及其他处罚。

### Increased Monetary Penalties
### 提高罚款金额

The Revised DAL increases monetary penalties for prohibited acts. For example, the potential fines for manufacturing or distributing a drug without a license, and for manufacturing or distributing counterfeit drugs, have increased from 2 to 5 times the value of the goods, to 15 to 30 times the value of the goods with a minimum fine of RMB 1,500,000 (about USD 208,000). Those who seek compensation under the law for quality issues (see below) may also request punitive sums in the amounts of 10 times the purchase price or three times the loss caused.
修订版《药品管理法》提高了对被禁止行为的罚款金额。例如，无证生产或经营药品以及生产或经营假药可能面临的处罚从货值金额的 2 至 5 倍扩大至 15 至 30 倍，最低罚金为 150 万元人民币（约 208,000 美元）。依法就质量问题寻求补偿者（见下文）亦可申请相当于购买价格 10 倍或所导致损失三倍的惩罚性赔偿。

### "First-Responsible-Party" Compensation Mechanism
### "首负责任"赔偿机制

The Revised DAL also establishes a "first party to be responsible" compensation mechanism, meaning whichever party (MAH, manufacturer, distributor, or hospital) first receives a claim as to quality issues is responsible for compensation if the claim is determined to be valid.
修订版《药品管理法》还建立了"首负责任"赔偿机制，即无论哪一方（药品上市许可持有人、药品生产企业、药品经营企业或医疗机构）先接到与质量问题相关的赔偿请求，如认定请求有效，应负责先行赔付。

### Increased Liability at the Individual-Level
### 扩大的个人责任

The Revised DAL explicitly provides that legal representatives[61] and executives in charge may be individually liable for prohibited acts, including monetary fines and debarment sanctions. The maximum penalty is now lifetime debarment from the pharmaceutical industry in certain cases.
修订版《药品管理法》明确规定，法定代表人[62]和主要负责人对被禁止行为负有个人责任，包括金钱处罚和禁止从业制裁。目前最大的处罚是在特定情况下终身禁止从事药品生产经营活动。

## No Patent Linkage or Regulatory Data Protection Provisions
## 无专利链接或监管数据保护规定

Earlier policy documents proposed to establish in China a patent linkage system, regulatory data protection, and patent term extension for innovative drugs.[63] These initiatives, however, were not included in the Revised DAL. Patent term extension was included in the latest draft of

the Patent Law, which has not been finalized. Patent linkage and regulatory data protection have been included in NMPA proposed rules to some extent, but the agency has not finalized any of these rules.
较早的政策文件提议在中国建立专利链接制度、监管数据保护及创新药专利期限补偿。[64]但是，这些倡议并未包含在修订版《药品管理法》中。专利期限补偿包含在最新的《专利法》修订草案（尚未修订完成）中。专利链接和监管数据保护在一定程度上包含在了国家药监局的法规征求意见中，但该机构尚未完善这些法规。

If you have any questions concerning the material discussed in this client alert, please contact the following China-focused members of our Food, Drugs, and Devices practice[65]:
如果您对本客户期刊中讨论的内容有任何疑问，请联系本所食品、药品和医疗器械业务团队专注于中国业务的下列成员：[66]


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[1] The Drug Administration Law (Standing Comm. Nat'l People's Cong., 2019), available at: http://www.nmpa.gov.cn/WS04/CL2076/357712.html. The first DAL was promulgated in 1984, and then revised comprehensively in 2001. Minor amendments were made in 2013 and 2015.

[2] 《药品管理法》（全国人大常委会，2019 年），参见：http://www.nmpa.gov.cn/WS04/CL2076/357712.html。《药品管理法》第一版于 1984 年颁布，后于 2001 年进行全面修订。2013 年和 2015 年进行了小幅修订。

[3] Decision on Authorizing the State Council to Implement the Drug MAH Pilot Program in Certain Areas (Standing Comm. Nat'l People's Cong., 2015), available at: http://www.gov.cn/xinwen/2015-11/04/content_5004817.htm; Decision of the Standing Committee of the National People's Congress on Extending the Period of Authorizing the State Council to Carry out the Pilot Program of Drug Marketing Licenses Holders System in Certain Areas (Standing Comm. Nat'l People's Cong., 2018), available at: http://www.gov.cn/xinwen/2018-10/27/content_5334906.htm

[4] 《关于授权国务院在部分地方开展药品上市许可持有人制度试点和有关问题的决定》（全国人大常委会，2015 年），参见：http://www.gov.cn/xinwen/2015-11/04/content_5004817.htm；《全国人民代表大会常务委员会关于延长授权国务院在部分地方开展药品上市许可持有人制度试点期限的决定》（全国人大常委会，2018 年），参见：http://www.gov.cn/xinwen/2018-10/27/content_5334906.htm。

[5] Notice for Issuing the Drug MAH Pilot Plan (State Council General Office No. 41, 2016), available at www.gov.cn/zhengce/content/2016-06/06/content_5079954.htm.

[6] 《关于印发药品上市许可持有人制度试点方案的通知》（国务院办公厅，国办发[2016]41 号），参见：www.gov.cn/zhengce/content/2016-06/06/content_5079954.htm。

[7] Supra note 1, Article 38. The PRC entity should be jointly and severally liable with the foreign MAH.

[8] 见前注 1，第 38 条。中国境内实体应当与境外药品上市许可持有人承担连带责任。

[9] Supra note 1, Article 30.

[10] Report on the Implementation of "Decision on Authorizing the State Council to Implement the Drug MAH Pilot Program in Certain Areas" (State Council, 2018), available at: http://www.sohu.com/a/273285261_803087.

[11] 见前注 1，第 30 条。

[12] 关于《全国人民代表大会常务委员会关于授权国务院在部分地方开展药品上市许可持有人制度试点和有关问题的决定》 实施情况的报告（国务院，2018 年），参见：http://www.sohu.com/a/273285261_803087。
[13] Supra note 1, Article 40.

[14] 见前注 1，第 40 条。
[15] The Opinions on Deepening Reform of the Review and Approval System to Encourage Innovations of Drugs and Medical Devices (CPC Central Committee General Office and State Council General Office 2017), available at http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm.

[16] 《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（中共中央办公厅与国务院办公厅，2017 年），参见：http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm。
[17] Under NMPA's current policy, priority review is available for certain drugs that treat serious or life-threatening conditions, including new drugs for the treatment of HIV, cancer or orphan diseases, and new drugs that treat unmet medical needs. NMPA's new priority categories over the past two years include drugs that treat diseases prevalent among children and elderly people, drugs that are on national scientific research plans, foreign innovative drugs that transfer manufacturing to China, and drugs that are being developed simultaneously in the United States and Europe.

[18] Supra note 1, Article 16 and 96.

[19] 根据国家药监局目前的政策，对于治疗严重或危及生命疾病的某些药物给予优先审评，这些药物包括治疗 HIV、癌症或罕见病的新药以及满足临床急需的新药。国家药监局在过去两年的优先审评新分类包括治疗儿童和老年人常见病的药物、列入国家科研计划的药物、转到中国生产的外国 创新药以及正在美国和欧洲同步开发的药物。
[20] 见前注 1，第 16 条和 96 条。
[21] Notice on Several Issues Related to the Evaluation on the Consistency of Generic Drugs Quality and Efficacy (NMPA No. 100, 2017), available at: http://samr.cfda.gov.cn/WS01/CL1757/176734.html.

[22] Regulation on the Administration of Drug Clinical Trial Institutions (Draft for Comments) (NMPA, 2017), available at: http://www.nmpa.gov.cn/WS04/CL2095/229367.html.

[23] 《关于仿制药质量和疗效一致性评价工作有关事项的公告》（食品药品监管总局，2017 年第 100 号），参见：http://samr.cfda.gov.cn/WS01/CL1757/176734.html。
[24] 《药物临床试验机构管理规定（征求意见稿）》（食品药品监管总局，2017 年），参见：http://www.nmpa.gov.cn/WS04/CL2095/229367.html l
[25] Drug Administration Law of the People's Republic of China, Article 2 (Standing Comm. Nat'l People's Cong., 2019), available at: http://www.npc.gov.cn/npc/c30834/201908/26a6b28dd83546d79d17f90c62e59461.shtml.

[26] The prior DAL stated including this list: traditional Chinese herbal medicines, prepared slices of traditional Chinese medicines, traditional Chinese patent medicine, active chemical pharmaceutical ingredients and their preparations, antibiotics, biochemical drugs, radiopharmaceuticals, serum, vaccines, blood products and diagnostic drugs."
[27] 《中华人民共和国药品管理法》第 2 条（全国人大常委会，2019 年），参见：http://www.npc.gov.cn/npc/c30834/201908/26a6b28dd83546d79d17f90c62e59461.shtml。
[28] 之前包含此清单的药品管理法称：中药材、中药饮片、中成药、化学原料药及其制剂、抗生素、生物化学药品、放射性药品、血清、疫苗、血液制品和诊断药品。
[29] Supra note 1, at Art. 45.

[30] 见前注 1，第 45 条。
[31] Supra note 1, Article 25.

[32] Notice on Adjusting the Review and Approval Process of API, Pharmaceutical Excipients and Packages (NMPA No. 146, 2017), available at: http://samr.cfda.gov.cn/WS01/CL0087/217747.html.

[33] 见前注 1，第 25 条。
[34] 《关于调整原料药、药用辅料和药包材审评审批事项的公告》（食品药品监管总局，2017 年第 146 号），参见：http://samr.cfda.gov.cn/WS01/CL0087/217747.html。
[35] Supra note 1, Article 61.

[36] 见前注 1，第 61 条。
[37] Market Entry Negative List (NDRC and MOFCOM, 2018), available at: http://tgs.ndrc.gov.cn/fmqd/qdxz/201812/P020181225324125390049.pdf.

[38] See http://www.gov.cn/zhengce/2019-08/26/content_5424729.htm.

[39] 《市场准入负面清单》（国家发改委和商务部，2018 年），参见：http://tgs.ndrc.gov.cn/fmqd/qdxz/201812/P020181225324125390049.pdf
[40] 参见 http://www.gov.cn/zhengce/2019-08/26/content_5424729.htm
[41] Supra note 1, Article 36 and Chapter 7.

[42] Supra note 1, Article 7.

[43] 见前注 1，第 36 条和第 7 章。
[44] 见前注 1，第 7 条。
[45] The Guidance on the Construction of Drug Information Traceability System (NMPA No. 35, 2018), available at: http://www.nmpa.gov.cn/WS04/CL2196/331501.html; and Basic Technical Requirements for Drug Traceability System, (NMPA No. 67, 2019), available at: http://www.nmpa.gov.cn/WS04/CL2138/357732.html.

[46] Supra note 30.

[47] 《关于药品信息化追溯体系建设的指导意见》（国家药监局，2018 年第 35 号），参见：http://www.nmpa.gov.cn/WS04/CL2138/357732.html；《药品追溯系统基本技术要求》（国家药监局，2019 年第 67 号），参见：http://www.nmpa.gov.cn/WS04/CL2138/357732.html。
[48] 见前注 30。
[49] Supra note 1, Article 12.

[50] 见前注 1，第 12 条。
[51] Supra note 1, Article 82.

[52] Supra note 1, Article 81 and 82.

[53] 见前注 1，第 82 条。
[54] 见前注 1，第 81 条和 82 条。
[55] Supra note 1, Article 23.

[56] 见前注 1，第 23 条。
[57] Drug Administration Law of the People's Republic of China, Article 48 (Standing Comm. Nat'l People's Cong., 2015), available at: http://www.npc.gov.cn/wxzl/gongbao/2015-07/06/content_1942838.htm.

[58] Supra note 1, Article 124.

[59] 《中华人民共和国药品管理法》（全国人大常委会，2015 年），参见：http://www.npc.gov.cn/wxzl/gongbao/2015-07/06/content_1942838.htm

[60] 见前注 1，第 124 条。

[61] The "legal representative" refers to the person listed on the corporate registration documents in accordance with the law or the articles of association of a legal entity, who acts on behalf of a legal entity in performing civil activities, not the lawyer.

[62] "法定代表人"指根据法律和法人实体章程列于公司注册文件、代表法人实体从事民事活动的人，并非指律师。

[63] Supra note 8.

[64] 见前注 16。

[65] Meng Pu, Runze Li and Kexin Yang also contributed to the research and writing of this alert.

[66] 蒲萌、李润泽和杨可欣也对本期刊的研究和撰写作出了贡献。