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Newly Revised *Drug Administration Law* Adopted After Deliberation —To Comprehensively Implement the *Four Strictest* Requirements and Effectively Protect Drug Safety for the Public

Closed in Beijing on August 26, 2019, the Twelfth Session of the Standing Committee of the 13th National People's Congress adopted the Revised Edition of the *Drug Administration Law of the People's Republic of China*, which shall be put in force as from December 1, 2019, marking the second systematic and structural major revision of the Law since its promulgation in 1984. The remarkable results of pharmaceutical reforms and effective practices were transformed into laws to beef up rule of law for public health.

Summarize the results of reforms with comprehensive & systematic revision

The *Drug Administration Law* (DAL) constitutes the basic law for drug supervision in China. The current DAL was enacted in 1984, first overhauled in 2001, and partially revised in 2013 and 2015. The promulgation and implementation of DAL has played a huge role in regulating drug production and management activities, strengthening drug supervision and management, ensuring the safety of public drug use, and promoting the development of the pharmaceutical industry. However, with the development of the social economy and the pharmaceutical industry, gaps loomed large between the current DAL and the new requirements of the CPC Party Central Committee and the State Council on drug safety, the new expectations of the people for drug safety, and the new situation facing drug supervision and industrial development, featuring the scarcity of measures to encourage innovation, inadequate penalties for illegal acts, and relatively backward scientific supervision methods. To adapt to the current new requirements, new expectations, and new situation, further improve drug safety governance system and drug safety management capabilities, the 12th and 13th National People's Congress Standing Committee incorporated DAL Amendment into their five-year legislation planning to accelerate the revision.

In October 2018, the *DAL Amendment Draft* was submitted to the Sixth Session of the Standing Committee of the 13th National People's Congress for initial deliberation, and subsequent solicitation of public comments. During the deliberation, taken into account that no major revisions have been made since the DAL revision in 2001, it was recommended that the results of the reform of the pharmaceutical sector and effective practices over the years be raised to the law, and the draft amendments be changed to the revised drafts. In April 2019, the Tenth Session of the Standing Committee of the 13th National People's Congress deliberated the Revised Draft of DAL, which has been passed by voting on August 26, 2019 at the third deliberation of the Twelfth Session of the Standing Committee of the 13th National People's Congress.

The newly revised DAL fully implements the *Four Strictest* requirements of the Party Central Committee on drug safety, clarifies the mission of drug administration as *protecting and promoting public health*, establishes the focus on people's health, and adheres to the basic principles of risk control, whole process supervision and

新修订《药品管理法》审议通过 ——全面贯彻落实“四个最严”有效保障公众用药安全

2019年8月26日，第十三届全国人大常委会第十二次会议在北京闭幕，会议表决通过《中华人民共和国药品管理法》修订案。新修订《药品管理法》将于2019年12月1日施行。这是《药品管理法》自1984年颁布以来的第二次系统性、结构性的重大修改，将药品领域改革成果和行之有效的做法上升为法律，为公众健康提供更有力的法治保障。

总结改革成果 全面系统修订

《药品管理法》是我国药品监管的基本法律。现行《药品管理法》于1984年制定，2001年首次全面修订，2013年和2015年两次修正部分条款。《药品管理法》的颁布实施，对于规范药品生产经营活动，加强药品监督管理，保障公众用药安全，促进药品产业发展，发挥了巨大作用。但是，随着社会经济以及药品产业的发展，现行《药品管理法》与党中央、国务院对药品安全的新要求，与人民群众对药品安全的新期待，与药品监管工作和产业发展面临的新形势等都存在一定差距，鼓励创新的措施不多，违法行为处罚的力度不够，科学监管手段相对滞后。为适应当前的新要求、新期待、新形势，进一步完善药品安全治理体系，提升药品安全治理能力，第十二届、第十三届全国人大常委会将《药品管理法》修订纳入五年立法规划，加快推进修订工作。

2018年10月，《药品管理法(修正草案)》提交第十三届全国人大常委会第六次会议进行初次审议，并于会后公开征求社会公众意见。审议中，有意见提出现行《药品管理法》自2001年修订以来，没有进行大的修改，建议将历年来药品领域改革成果和行之有效的做法上升为法律，将修正草案改为修订草案。2019年4月，第十三届全国人大常委会第十次会议对《药品管理法(修订草案)》进行审议。2019年8月26日，第十三届全国人大常委会第十二次会议进行第三次审议并表决通过。

新修订《药品管理法》全面贯彻落实党中央有关药品安全“四个最严”要求，明确了保护和促进公众健康的药品管理工作使命，确立

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collateral social supervision, requiring the establishment of a scientific and strict supervision and management system to comprehensively improve the quality of medicines and ensure their safety, effectiveness and accessibility. These fully embody DAL Revision's adherence to people-centredness, problem-oriented solutions, respect of law, international perspective, reform & innovation, as well as the unequivocal position, fundamental compliance and basic requirements of the scientific development.

Encourage R&D to Ensure Accessible Supply

In August 2015, the State Council issued the *Opinions on Reforming the Review & Approval System for Drugs and Medical Devices* (the State Council [2015] No. 44). In October 2017, the General Offices of the CPC Party Committee and the State Council issued the *Opinions on Deepening the Reform of Review & Approval System to Encourage Innovation in Drugs and Medical Devices* (General Office [2017] No. 42), focusing on the five themes of *innovation, quality, efficiency, system, and capability*, proposed to encourage drug R&D innovation, carry out pilot programs for Marketing Authorization Holders, reform clinic trial management protocols, accelerate marketing review and approval, and a series of other major reform measures with historical and innovative significance. In the past few years, the drug administration reform has been vigorously promoted and achieved remarkable results. The newly revised DAL has solidified the effective reform measures into legal results to encourage the R&D and innovation of new drugs, and laid a more solid legal foundation for further reform of the pharmaceutical sector.

DAL supports drug innovations that are clinically value-oriented and have a clear or specific therapeutic effect on human diseases. It encourages the R&D of new drugs with new therapeutic mechanisms, new drugs for treatment of serious life-threatening diseases or orphan diseases, and new drugs with multi-targeted systemic regulatory interventions, and encourages the R&D and innovation of drugs for pediatric use.

Establish and improve the drug review & approval system. Improve the efficiency and optimize the review and approval process through a series of measures, encompassing the establishment of communication and exchange, expert consultation and other systems; the transformation of clinical trial examination & approval system to the implied licensing system within a timeline; and the record-filing management for bioequivalence tests and drug clinical trial institutions.

Meanwhile, DAL will give priority to the review and approval of short supplied new drugs and pediatric drugs catering to urgent clinical needs, drugs for the prevention of major infectious diseases and rare diseases; as well as to conditioned marketing approval for drugs against diseases that are seriously life-threatening and have no proven effective treatment, and drugs urgently needed for public health.

All sectors of the society pay close attention to the shortage of commonly used drugs and emergency (first aid) drugs in China. The newly revised DAL provides a special Chapter on *Pharmaceutical Reserves and Supplies*, clarifying the state's drug reserve system, drug supply & demand monitoring system, list management system and prioritized drug review system for short-supplied drugs, involving multiple departments' synergy to strengthen drug supply security.

Adhere to whole process management & control to ensure that the responsibilities of various parties are well met

Drug safety is closely related to public life and health. On the basis of earnestly

了以人民健康为中心，坚持风险管理、全程管控、社会共治的基本原则，要求建立科学、严格的监督管理制度，全面提升药品质量，保障药品的安全、有效、可及。这些充分体现了《药品管理法》的修订，坚持以人为本、坚持问题导向、坚持尊重规律、坚持国际视野、坚持改革创新、坚持科学发展的鲜明立场、根本遵循和基本要求。

鼓励研制创新 保障供应可及

2015年8月，国务院印发《关于改革药品医疗器械审评审批制度的意见》(国发〔2015〕44号)，2017年10月，中办、国办印发《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》(厅字〔2017〕42号)，围绕“创新、质量、效率、体系、能力”五大主题，提出鼓励药物研发创新、开展药品上市许可持有人制度试点、改革临床试验管理、加快上市审评审批等一系列具有历史性、创新性意义的重大改革措施。几年来，药品监管改革创新有力推进，取得显著成效。新修订《药品管理法》将行之有效的改革措施固化为法律成果，鼓励研制和创新新药，为深入推进药品领域改革奠定了更为坚实的法律基础。

支持以临床价值为导向、对人体疾病具有明确或者特殊疗效的药物创新。鼓励对具有新的治疗机理、治疗严重危及生命的疾病或者罕见病、对人体具有多靶向系统性调节干预功能等的新药研制，鼓励儿童用药品的研制和创新。

建立健全药品审评审批制度。通过一系列措施提高审评审批效率，优化审评审批流程。如建立沟通交流、专家咨询等制度，将临床试验由审批制改为到期默示许可制，对生物等效性试验以及药物临床试验机构实行备案管理。

同时，对临床急需的短缺药品、防治重大传染病和罕见病等疾病的新药、儿童用药品优先审评审批；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，可以附带条件批准上市。

社会各界高度关注我国常用药、急(抢)救药短缺问题，新修订《药品管理法》对“药品储备和供应”做出专章规定，明确国家实行药品储备制度、国家建立药品供求监测体系、国家实行短缺药品清单管理制度，国家实行短缺药品优先审评制度等，多部门共同加强药品供应保障工作。

坚持全程管控 落实各方责任

药品安全关乎公众生命健康，在认真总结国际社会药品管理经验的基础上，新修订

summarizing the experience of drug management in the international community, the newly revised DAL further clarifies that drug safety should follow the basic principles of *risk management, full process control, and social co-governance*. Taking the Drug Marketing Authorization Holder (MAH) System as the main line, further clarify the quality and safety responsibility of the drug life cycle, and firmly defend the public safety bottom line.

The drug MAH is responsible for the effectiveness and quality reliability of the drug during the whole process of drug R&D, production, distribution and use. The newly revised DAL has an ad hoc Third Chapter: *Marketing Authorization Holder*, which provides comprehensive and systematic regulations on the conditions, rights, obligations and responsibilities of the MAH.

It highlights the whole process information requirements for drugs. The engagement of drug R&D, production, distribution and use shall follow laws, regulations, rules, standards and norms to ensure that the information in the whole process is true, accurate, complete and traceable.

The newly revised DAL also imposes strict regulations for the R&D, production and circulation of pharmaceuticals. It is stipulated that the development of drugs should follow the Good Laboratory Practice for Non-Clinical Laboratory Studies and GCP, and ensure that the whole process of drug R&D consistently meets the statutory requirements. The MAH shall establish a drug quality assurance system and strictly supervise drug-marketing release. The MAH shall comprehensively evaluate and verify the impact of alterations items on the safety, effectiveness and quality controllability of drugs per the national regulations. At the same time, the MAH should be required to establish and implement a traceability system to ensure traceability of drugs.

The newly revised DAL also sets clear requirements for post-marketing management of drugs. It is stipulated that an annual reporting system shall be established, and the MAH shall report the production and sales of drugs, post-marketing research, risk management, etc. to the drug regulatory authorities in accordance with regulations. Furthermore, the MAH should take the initiative to carry out the post-marketing research, further confirm the drug safety, effectiveness and quality controllability, and take timely risk control measures for drugs with identified risks. If damage is caused to the drug user, the liability shall be borne by the MAH according to law.

In addition, the newly revised DAL has strengthened the drug life cycle management concept from the aspects of pharmacovigilance, supervision and inspection, credit management, and emergency response, refined and improved the treatment measures of the drug regulatory authorities to improve the efficiency of supervision.

The revision also reiterated the concept of *social co-governance* for drug safety, highlighting the responsibilities of local governments, relevant departments, pharmaceutical industry associations, news media, etc., and their synergy to ensure drug safety.

Severe and well-placed punishment for serious violations of the law

The newly revised DAL comprehensively augmented the penalties for illegal acts and specifically stipulates in Articles that if a crime is committed in violation of the provisions of this Law, criminal responsibility shall be investigated according to law, and high-pressure punishment upon illegal and criminal activities endangering drug safety shall be maintained in a clear-cut manner.

Augmented the penalties to offenders in terms of property. For illegal activities such as unlicensed production and distribution, production and sale of counterfeit drugs, the amount of fines rose from 2-5 times the value of the medicines unlawfully made or sold (including both sold and unsold pharmaceuticals, which also applies below) to 15-30 times, where the value is less than RMB 100,000, it is uniformly counted as RMB 100,000: that is, the minimum fine is RMB 1.5 million. The fine for the

《药品管理法》进一步明确药品安全工作应当遵循“风险管理、全程管控、社会共治”的基本原则，并以实施药品上市许可持有人制度为主线，进一步明确药品全生命周期质量安全责任，坚决守住公共安全底线。

药品上市许可持有人依法对药品研制、生产、经营、使用全过程中的药品安全性、有效性和质量可靠性负责。新修订《药品管理法》专设第三章“药品上市许可持有人”，对持有人的条件、权利、义务、责任等做出了全面系统的规定。

新修订《药品管理法》强化药品全过程信息要求。从事药品研制、生产、经营、使用活动，应当遵循法律、法规、规章、标准和规范，保证全过程信息真实、准确、完整和可追溯。

对药品研制、生产、流通环节，新修订《药品管理法》也予以严格管理。规定从事药品研制，应当遵循药物非临床研究质量管理规范、药物临床试验质量管理规范，保障药品研制全过程持续符合法定要求。规定持有人应当建立药品质量保证体系，严格药品上市放行。持有人应当按照国家规定全面评估、验证变更事项对药品安全性、有效性和质量可控性的影响。同时要求持有人应当建立并实施追溯制度，保证药品可追溯。

新修订《药品管理法》对药品上市后管理也提出了明确要求。规定建立年度报告制度，持有人每年将药品生产销售、上市后研究、风险管理等情况按照规定向药品监管部门报告。同时持有人应当主动开展药品上市后研究，对药品安全性、有效性和质量可控性进行进一步确证，对已识别风险的药品及时采取风险控制措施。给用药者造成损害的，依法承担赔偿责任。

此外，新修订《药品管理法》还从药物警戒、监督检查、信用管理、应急处置等方面强化了药品全生命周期管理理念的落实，细化完善了药品监管部门的处理措施，提升监管效能。

此次修订还强化了药品安全“社会共治”的理念，强化了地方政府、有关部门、药品行业协会、新闻媒体等各方面的责任，齐心合力共同保障药品安全。

严惩重处违法 落实处罚到人

新修订《药品管理法》全面加大对违法行为的处罚力度，专条规定，违反本法规定，构成犯罪的，依法追究刑事责任，旗帜鲜明地保持对药品安全犯罪行为的高压态势。

提高了财产罚幅度。如对无证生产经营、生产销售假药等违法行为，罚款数额由货值金额的二倍到五倍提高到十五倍到三十

production and sale of substandard drugs is also increased from 1-3 times the value of goods to 10-20 times.

Augmented the penalties to offenders in terms of qualifications. The qualification penalty for the responsible person for counterfeit and substandard drugs shall be escalated from ten years ban to lifelong ban from the industry. For enterprises whose licenses are revoked for the production and sale of counterfeit drugs, their corresponding applications shall not be accepted within ten years.

Added the penalties in terms of personal freedom. The public security organs may detain the relevant responsible personnel for 5-15 days for illegal production and sale of counterfeit and substandard drugs with serious consequences, as well as the falsification, fabrication or acquisition of licenses by fraud.

For enterprises seriously violating the law, the newly revised DAL implements *specific and targeted penalty to offenders*, while the enterprise is being punished per law, its legal representative, principal responsible person, directly responsible person in charge and other responsible personnel shall also be subject to punishment, including confiscation of the income earned during the period of the violation, fines, and ban from the industry for a certain period of time or even a lifetime.

The newly revised DAL also improved the civil liability system. Including the clarification of liabilities of the drug MAH and manufacturer and distributor for damage; the stipulation that the agent of overseas MAH shall be jointly and severally liable with the MAH; the effectuation of charge-back system for civil liability; and the punitive damages the victim may request for the production of counterfeit and substandard drug, and intentional sale or use of it.

While beefing up the penalties for violations, the newly revised DAL strictly implements the principle of *offense-punishment equivalency*, distinguishing between minor illegal activities and serious violations with grave consequences, and focuses on cracking down serious illegal acts or those with subjective intent. (August 26, 2019)

倍，货值金额不足十万元的以十万元计，也就是最低罚款一百五十万元。生产销售劣药违法行为的罚款，也从货值金额的一倍到三倍提高到十倍到二十倍。

加大了资格罚力度。对假劣药违法行为责任人的资格罚由十年禁业提高到终身禁业，对生产销售假药被吊销许可证的企业，十年内不受理其相应申请。

增加了自由罚手段。对生产销售假药和生产销售劣药情节严重的，以及伪造编造许可证件、骗取许可证件等情节恶劣的违法行为，可以由公安机关对相关责任人员处五日至十五日的拘留。

对严重违法的企业，新修订《药品管理法》落实“处罚到人”，在对企业依法处罚的同时，对企业法定代表人、主要负责人、直接负责的主管人员和其他责任人员也予以处罚，包括没收违法行为发生期间其所获收入、罚款、一定期限甚至终身禁业等。

新修订《药品管理法》还完善了民事责任制度。包括明确药品上市许可持有人和药品生产经营企业赔偿责任；规定境外药品上市许可持有人在中国境内的代理人与持有人承担连带责任;实行民事赔偿首负责任制;对生产假劣药或者明知假劣药仍销售使用的，受害人可以要求惩罚性赔偿等。

在大幅提升对违法行为的处罚力度时，新修订的《药品管理法》严格贯彻“过罚相当”的原则，区分一般违法行为和情节严重、造成严重后果的违法行为，重点加大对主观故意或者严重违法行为的惩处力度。

(2019-08-26)

NMPA Issued the *Guiding Principles for Capacity Building of Drug Inspection and Testing Institutions*

The drug inspection and testing system constitutes an important part of the drug regulatory system. Per the relevant requirements of the *Thirteenth Five-Year Plan for National Drug Safety* and the *Construction Standards for Drug Inspection and Testing Centers* (*Institutions and Institutes*) (Construction Standard 187-2017), to strengthen the guidance over drug inspection and testing institutions in capacity building and improve their corresponding capabilities, NMPA has organized the formulation of and released on August 30, 2019 the Guiding Principles for Capacity Building of Drug Inspection and Testing Institutions.

(August 30, 2019)

国家药品监督管理局印发《药品检验检测机构能力建设指导原则》

药品检验检测体系是药品监管体系的重要组成部分，按照《“十三五”国家药品安全规划》及《药品检验检测中心（院、所）建设标准》（建标187-2017）有关要求，为加强对药品检验检测机构在能力建设方面的指导，提升检验检测能力，国家药品监督管理局组织制定了《药品检验检测机构能力建设指导原则》，于2019年8月30日印发。

（2019-08-30）

NMPA Issued Three Informationization Standards such as the Basic Technical Requirements for Drug Traceability System

To implement the provisions of the *Vaccine Administration Law of the People's Republic of China*, per the *Guiding Opinions on the Construction of Drug Informationization Traceability System* (NMPA Department of Drug Supervision (2018) No. 35) and other documents, NMPA has organized the formulation of three Informationization Standards: the Basic Technical Requirements for Drug Traceability System, Basic Dataset for Vaccine Traceability, and Basic Technical Requirements for Vaccine Traceability Data Exchange, which were released on August 27, 2019, and effective as of the date of publication. (August 27, 2019)

国家药品监督管理局发布《药品追溯系统基本技术要求》等3项信息化

为贯彻落实《中华人民共和国疫苗管理法》规定，按照《关于药品信息化追溯体系建设的指导意见》（国药监药管〔2018〕35号）等文件要求，国家药监局组织制订了《药品追溯系统基本技术要求》《疫苗追溯基本数据集》《疫苗追溯数据交换基本技术要求》等3项信息化标准，于2019年8月27日发布，自发布之日起实施。

（2019-08-27）

NMPA Issued the *Administrative Measures for Drug Quality Sampling Inspection*

On August 19, 2019, NMPA issued the *Administrative Measures for Drug Quality Sampling Inspection* (hereinafter referred to as the *Measures*), effective as of the date of promulgation. The SFDA *Notice on the Issuance of Regulations for Drug Quality Sampling Inspection* (SFDA Department of Market Supervision [2006] No. 379) shall be repealed simultaneously.

(August 19, 2019)

国家药品监督管理局发布《药品质量抽查检验管理办法》

2019年8月19日，国家药品监督管理局印发《药品质量抽查检验管理办法》（以下简称《办法》，《办法》自发布之日起实施。《国家食品药品监督管理局关于印发药品质量抽查检验管理规定的通知》（国食药监市〔2006〕379号）自《办法》发布之日起废止。

（2019-08-19）

NMPA Issued the *Notice on Enabling the New Version of the Drug Production License and other Certificates*

As per the *Drug Administration Law of the People's Republic of China*, the Regulations for Implementation of the Drug Administration Law of the People's Republic of China and the regulations on post-marketing supervision of pharmaceuticals, NMPA uniformly formulated the formats of *Drug Production License* and other Certificates. To standardize the formats and renewal of the drug administrative licenses, on August 7, 2019, NMPA issued the *Notice on Enabling the New Version of the Drug Production License and other Certificates*, and notified the relevant matters as follows:

1. NMPA shall uniformly formulate the formats of new versions of the *Drug Production License, Medical Institution Preparation License, Pharmaceutical Preparation Certificate for Medical Institution, Radioactive Drug Production License, Radioactive Drug Distribution License* and *Radioactive Drug Use License*, and *Internet Drug Information Service Qualification Certificate* (including original and copy). The original and copy of the new certificates must indicate the daily regulatory agency and phone numbers for supervisory report, implement the supervisory responsibility, and accept social supervision.
2. The new version licenses shall be enabled as from September 1, 2019. The drug regulatory authorities of the provinces (autonomous regions and

国家药品监督管理局发布《关于启用新版<药品生产许可证>等许可证书的通知》

根据《中华人民共和国药品管理法》和《中华人民共和国药品管理法实施条例》及有关药品上市后监管的法规规定，国家药品监督管理部门统一制定《药品生产许可证》等许可证书样式。为规范药品行政许可证明文件样式和换发工作，2019年8月7日，国家药监局发布《关于启用新版<药品生产许可证>等许可证书的通知》，将有关事宜通知如下：

一、国家药品监督管理局统一制定新版《药品生产许可证》《医疗机构制剂许可证》《药品经营许可证》《放射性药品生产许可证》《放射性药品经营许可证》《放射性药品使用许可证》《互联网药品信息服务资格证书》（包括正、副本）等7种许可证书样式。新版证书的正、副本上须注明日常监管机构和监督举报电话，落实监管责任，

municipalities) shall issue relevant certificates to the new applicants in the new formats.

In areas where electronic certificates are issued and used, the e-Cert style should be consistent with the new version of the paper certificates.

3. The Drug Administration of all provinces (autonomous regions, municipalities) shall attach great importance to the renewal of the new version of the license, with careful deployment taking into account the actual situation, to ensure smooth and orderly replacements. It is necessary to clearly indicate the handling standards, procedures and time limit, and perform strict review. Where requirements are not met, the certificates shall not be renewed.

4. To facilitate unified management, the licenses not to be expired in 2019 shall be replaced by the Drug Administration of all provinces (autonomous regions, municipalities) before the end of December 2020, with validity period selfsame as the original certificates.

5. Should any problems and suggestions arise therein, please contact the NMPA Department of Drug Supervision in time.

(August 7, 2019)

接受社会监督。

二、新版许可证书样式自2019年9月1日起启用，各省（区、市）药品监督管理局应按照新版许可证书样式向新申领单位核发相关证书。

发放、使用电子证书的地区，电子证书样式应当与新版纸质证书样式保持一致。

三、各省（区、市）药品监督管理局要高度重视此次新版许可证的换发工作，结合实际周密部署，确保换证工作平稳有序。要明示办理标准、程序要求，按照时限办理，严格审查把关。不符合要求的，不予换证。

四、为便于统一管理，对2019年尚未到期的许可证书，由各省（区、市）药品监督管理局组织在2020年12月底前为其更换新版许可证，有效期与原证一致。

五、在换证工作中如有问题和建议，请及时与国家药监局药品监管司联系。

（2019-08-07）

NMPA, Ministry of Public Security, National Health Commission issued the *Announcement on the Inclusion of Oxycodone-Containing Compound Preparations in the Management of Psychotropic Substances*

Per the relevant Regulation for the Control of Narcotic Drugs and Psychotropic Substances, on August 6, 2019, NMPA, the Ministry of Public Security, and the National Health Commission decided to include oxycodone-containing compound preparations in the management of psychotropic substances. The Announcement reads as follows:

1. Oral solid preparations containing more than 5 mg of oxycodone base per dose unit, barring other narcotic drugs, psychotropic drugs or pharmaceutical precursor chemicals, shall be subject to the management of Class I psychotropic drugs;

2. Oral solid preparations containing no more than 5 mg of oxycodone base per dose unit, barring other narcotic drugs, psychotropic drugs or pharmaceutical precursor chemicals, shall be subject to the management of Class II psychotropic drugs;

3. Compound oral solid preparations of buprenorphine and naloxone shall be subject to the management of Class II psychotropic drugs.

This Announcement shall come into force on September 1, 2019.

(August 6, 2019)

国家药品监督管理局 公安部 国家卫生健康委发布《关于将含羟考酮复方制剂等品种列入精神药品管理的公告》

根据《麻醉药品和精神药品管理条例》有关规定，2019年8月6日，国家药品监督管理局、公安部、国家卫生健康委员会决定将含羟考酮复方制剂等品种列入精神药品管理。公告如下：

一、口服固体制剂每剂量单位含羟考酮碱大于5毫克，且不含其它麻醉药品、精神药品或药品类易制毒化学品的复方制剂列入第一类精神药品管理；

二、口服固体制剂每剂量单位含羟考酮碱不超过5毫克，且不含其它麻醉药品、精神药品或药品类易制毒化学品的复方制剂列入第二类精神药品管理；

三、丁丙诺啡与纳洛酮的复方口服固体制剂列入第二类精神药品管理。

本公告自2019年9月1日起施行。

（2019-08-06）

Medical Devices

NMPA Issued the *Guiding Principles for Capacity Building of Medical Device Inspection and Testing Organizations*

Medical device inspection and testing system constitutes an important part of the medical device supervision system, per the *Thirteenth Five-Year Plan for National Drug Safety and the Construction Standards for Medical Device Inspection*

医疗器械

国家药品监督管理局印发《医疗器械检验检测机构能力建设指导原则》

医疗器械检验检测体系是医疗器械监管体系的重要组成部分，按照《“十三五”国

and Testing Centers (*Institutions, Institutes*) (Construction Standard 188-2017), etc., to strengthen the guidance over the capacity building of medical device inspection and testing institutions, and improve their corresponding capabilities, NMPA has organized the formulation of and released on August 30, 2019 the *Guiding Principles for Capacity Building of Medical Device Inspection and Testing Organizations*.

(August 30, 2019)

家药品安全规划》及《医疗器械检验检测中心（院、所）建设标准》（建标188-2017）等文件要求，为加强对医疗器械检验检测机构在能力建设方面的指导，提升检验检测能力，国家药品监督管理局组织制定了《医疗器械检验检测机构能力建设指导原则》，于2019年8月30日印发。 (2019-08-30)

NMPA Issued the Rules for Unique Identification System for Medical Devices

Per the *Notice of the General Office of the State Council on the Issuance of the Reform Plan for Governance over High-value Medical Consumables* (the State Council General Office [2019] No. 37), to standardize the construction of a unique identification system for medical devices, and strengthen the life cycle management of medical devices, based on the *Regulations for the Supervision and Administration of Medical Devices*, NMPA has formulated and promulgated on August 27, 2019 the *Rules for the Unique Identification System of Medical Devices*, which will go into effect as from October 1, 2019.

(August 27, 2019)

国家药品监督管理局发布医疗器械唯一标识系统规则

为贯彻落实《国务院办公厅关于印发治理高值医用耗材改革方案的通知》（国办发〔2019〕37号），规范医疗器械唯一标识系统建设，加强医疗器械全生命周期管理，依据《医疗器械监督管理条例》，国家药监局制定了《医疗器械唯一标识系统规则》，于2019年8月27日发布，自2019年10月1日起施行。 (2019-08-27)

Cosmetics

NMPA Issued the *Announcement on Implementing Work Specifications for Cosmetics Registration and Record-filing Inspection*

To standardize the registration and filing inspection of cosmetics, and ensure that the registration and filing inspection of cosmetics is open, fair, just and scientific, NMPA has formulated and released on September 10, 2019 the *Work Specifications for Cosmetics Registration and Record-filing Inspection*.

(September 10, 2019)

化妆品

国家药品监督管理局发布《关于实施化妆品注册和备案检验工作规范的公告》

为规范化妆品注册和备案检验工作，保证化妆品注册和备案检验工作公开、公平、公正、科学，国家药品监督管理局制定了《化妆品注册和备案检验工作规范》，于2019年9月10日发布。 (2019-09-10)

NMPA Issued the *Guiding Principles for Capacity Building of Cosmetics Inspection and Testing Institutions*

Cosmetics inspection and testing system constitutes an important part of the cosmetics regulatory system. Per the *Notice of the State Council on the Issuance of the Thirteenth Five-Year Plan for National Food Safety and National Drug Safety* (the State Council [2017] No. 12), etc., to reinforce the construction of cosmetics inspection and testing system, improve inspection and testing capabilities, and strengthen the guidance over cosmetics inspection and testing institutions in capacity building, NMPA has organized the formulation of and released on August 30, 2019 the *Guiding Principles for Capacity Building of Cosmetic Inspection and Testing Organizations*.

(August 30, 2019)

国家药品监督管理局印发《化妆品检验检测机构能力建设指导原则》

化妆品检验检测体系是化妆品监管体系的重要组成部分，根据《国务院关于印发“十三五”国家食品安全规划和“十三五”国家药品安全规划的通知》（国发〔2017〕12号）等文件要求，为加强化妆品检验检测体系建设，提升检验检测能力，强化对化妆品检验检测机构在能力建设方面的指导，国家药品监督管理局组织制定了《化妆品检验检测机构能力建设指导原则》，于2019年8月30日印发。 (2019-08-30)

General Information

New Version of *China Drug Administration* Mobile Application Online

Recently, the new version of NMPA's government website mobile application client *China Drug Administration* (hereinafter referred to as *CDA*) was released online. Standing at the user's point of view, the new version of *CDA* caters more to the user habits of public mobile applications, and to the public's demand for drug safety authority information.

New look of *Handheld Government Service*

To promote the *One Network, One Door, One Time (One Network Online Service, One Door Offline Service and One Time On-Site Service)* Reform and boost the public service level of the mobile application of NMPA government website, the new version of China Drug Administration has focused on creating government service sections. The Administrative Service Section comprehensively co-ordinates the functions related to NMPA departments, integrates the unified entry of government mobile applications, and continuously expands the scope of services along with the construction of government mobile applications. At present, CDA has integrated government service portals such as Government Affairs Hall, Local Drug Supervision, Data Enquiries, Complaints and Reports, etc. The user can easily find the entry for items to be handled in the Government Service Section, thus eliminating the distress of multi-party consultation and realizing "*more e-service, less errands*".

More convenient *Pocket Data query*

The new version of *China Drug Administration* has opened a Data Query Section to provide users with data services. The Section discloses information announced by NMPA for drugs, medical devices and cosmetics related products, enterprises and licensing progress, further optimized the data query methods and user experience, and provided two query methods: fuzzy query and single field query, to furnish the users with professional and authoritative data references. To pocket the regulatory data to users, the Data Query Section will continue to expand the data disclosure scope for the mobile terminal, providing more convenient services for the public, enterprises and supervisors.

(July 19, 2019)

综合信息

新版“中国药品监管”移动应用上线

近日，新版国家药监局政府网站移动应用客户端“中国药品监管”（以下简称“中国药监”）发布上线。新版“中国药监”站在用户的角度，更加贴合公众移动应用使用习惯，更加贴近公众对药品安全权威信息的需求。

“掌上政务服务”新气象

为推进“一网、一门、一次”改革，提升国家药监局政府网站移动应用服务公众的水平，新版“中国药监”着重打造了政务服务栏目。政务服务栏目综合统筹国家药监局职能相关的办事系统，集成政务移动应用统一入口，并不断根据政务移动应用的建设情况扩充服务范围。目前，“中国药监”已集成了政务大厅、地方药监、数据查询、投诉举报等政务服务入口。用户在政务服务栏目可以方便的找到办理事项的入口，省去了多方咨询的苦恼，实现“让信息多跑路，群众少跑腿”。

“口袋里的数据”查询更便捷

新版“中国药监”开设了数据查询栏目，向用户提供数据服务。数据查询栏目开放了国家药监局对外公布的药品、医疗器械、化妆品相关的产品、企业及许可进度信息，进一步优化数据查询方式和体验，提供了模糊查询和单一字段查询两种查询方式，为用户提供专业、权威的数据参考。为把监管数据揣进用户的口袋，数据查询栏目将不断扩充移动端的数据公开范围，为公众、企业、监管人员提供更加便捷的服务。

（2019-09-10）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
• For electronic version of the Newsletter please visit http://www.ccfdie.org

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。
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