2020. Volume 3

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

SAMR Promulgates the *Provisions for Drug Registration* and *Provisions for the Supervision and Administration of Drug Production*

On March 30, the State Administration for Market Regulation (SAMR) promulgated the *Provisions for Drug Registration* by Order No. 27, and the *Provisions for the Supervision and Administration of Drug Production* by Order No. 28, which shall be officially implemented from July 1, 2020.

The Party Committees of SAMR and NMPA have, heretofore, reviewed and revised the Drafts for Deliberation of the above Provisions pursuant to the *Legislation Law of the People's Republic of China*, the *Provisions for Drafting Procedures of Rules & Regulations,* and the *SAMR Provisions for Drafting Procedures of Rules & Regulations*; per the latest requirements of the newly enforced *Vaccine Administration Law of the People's Republic of China* and the newly revised *Drug Administration Law*; and on the basis of seriously implementing the decisions and deployment of the CPC Party Central Committee and the State Council on drug & vaccine regulatory reform, and adhering to the law-based reform consensus to promote various reforms and innovations in the field of drugs. In the process of drafting and reviewing, we adhered to the requirements of scientific, democratic, and law-based legislation, and listened to opinions and suggestions extensively. Aiming at the key and difficult issues in the revision, expert evaluations are specially organized to fully conduct research and demonstration. On January 15, the above two regulations were reviewed and approved by the 1st SAMR executive meeting in 2020.

In the drafting and revision process, four basic ideas were followed: First, adhere to the *Four Strictest (Strictest Standards, Regulation, Punishment, and Accountability)* requirements to regulate drug registration and production, strengthen the whole-process regulation, strictly prevent and control drug quality and safety risks, and firmly adhere to the bottom line of safeguarding public safety. Second, deepen reform and innovation to fully implement the Marketing Authorization Holder management system, encourage drug innovation, continue to optimize the drug registration review & approval system and drug production permit system, and build a scientific and efficient review & approval process. Third, highlight the people-centered, problem-oriented approach to draw on international regulatory practice and experience while taking into account the domestic situation, focus on solving the prominent issues in drug registration and production supervision, clarify the scope and expedite the marketing registration for short supplied, clinically urgently-needed drugs, pediatric drugs, orphan drugs, drugs against major infectious diseases, and urgently-needed vaccines for disease prevention & control. Specific requirements shall be made to ensure sustained compliance in pharmaceutical production. Fourth, strengthen accountability to strictly implement corporate principal responsibility and regulatory responsibilities, refine corporate obligations in drug R&D, registration, production and other links; and clarify the division of powers amongst regulatory authorities and the corresponding inspection requirements.

The revision of the two Provisions, which are the core supporting regulations in the field of drug supervision, will lay the foundation for the rule of law to strengthen drug quality and safety risk control, standardize and strengthen drug supervision, and ensure drug safety, effectiveness and quality control.

(March 30, 2020)

国家市场监督管理总局公布《药品注册管理办法》和《药品生产监督管理办法》

3月30日，国家市场监督管理总局以总局27号令公布《药品注册管理办法》，以28号令公布《药品生产监督管理办法》，两部规章将于2020年7月1日起正式施行。

国家市场监督管理总局党组、国家药品监督管理局党组认真贯彻落实党中央、国务院关于药品、疫苗监管改革的决策部署，坚持以法治凝聚改革共识，在法治轨道上推进药品领域的各项改革创新，落实新制定的《疫苗管理法》和新修订的《药品管理法》的最新要求，按照《立法法》《规章制定程序条例》《国家市场监督管理总局规章制定程序规定》，对两部规章送审稿进行了审查修改。在起草审查过程中，坚持科学立法、民主立法、依法立法要求，广泛听取意见建议。针对修订中的重点难点问题，专门组织专家评估，充分进行研究论证。1月15日，总局2020年第1次局务会议审议通过上述两部规章。

起草修订过程遵循的基本思路：一是坚持“四个最严”。严格药品注册管理和药品生产监管，强化全过程监管，严格防范和控制药品质量安全风险，坚决守住公共安全底线。二是深化改革创新。全面实施上市许可持有人管理制度，鼓励药品创新，持续优化药品注册审评审批制度和药品生产许可制度，构建科学高效审评审批流程。三是突出问题导向。坚持以人民为中心，借鉴国际监管实践经验，结合国内监管实际，重点解决药品注册和药品生产监管中的突出问题，将临床急需的短缺药、儿童用药、罕见病用药、重大传染病用药、疾病防控急需疫苗和创新疫苗等明确纳入加快上市注册范围。对药品生产中的持续合规提出明确要求。四是强化责任落实。严格落实企业主体责任和监管责任，细化药品研制、注册、生产等环节义务，明确监管部门的事权划分和监督检查要求。

作为药品监管领域的核心配套规章，两部规章的修订将为强化药品质量安全风险控制，规范和加强药品监管，保障药品安全、有效和质量可控奠定法治基础。（2020-03-30）

Published by
China Center for Food and Drug International Exchange
Servier (Tianjin) Pharmaceutical Co., Ltd.

NMPA Issued the *Announcement on Issues Pertaining to the Current Administration on Drug Distribution*

On April 3, 2020, NMPA issued the *Announcement on Issues Pertaining to the Current Administration on Drug Distribution*, which contains the following contents:

The newly revised *Drug Administration Law of the People's Republic of China* (hereinafter referred to as *Drug Administration Law*) came into force as of December 1, 2019, and the formulation of relevant supporting departmental rules and regulations is ongoing. To implement the relevant requirements of the *Drug Administration Law* and further clarify and standardize the supervision and management of drug distribution, the relevant matters are hereby announced:

1. As form the implementation of the newly revised *Drug Administration Law*, unless the promulgation of relevant supportive departmental regulations stated otherwise, the *Regulations on Drug Distribution License* (Former CFDA Order No. 6) and the *Provisions for Supervision of Drug Distribution (Formerly CFDA Order No. 26)*remains valid and, where their provisions are inconsistent with the *Drug Administration Law*, the latter shall prevail.
2. Where a newly establishing drug distributor applies for the issuance of a Drug Distribution License, the drug administration departments may combine the examination & approval procedures for establishment preparation and acceptance, and organize inspection over the applicant pursuant to the relevant requirements of the *Good Supply Practice for Pharmaceutical Products (GSP)* and on-site inspection guidelines. A Drug Distribution License shall be issued if requirements are met.
3. Where a drug distributor applies for renewal of a drug distribution license, the drug administration departments shall conduct a review in accordance with the procedures for renewal of licenses and relevant requirements for establishment. The license shall be renewed if the conditions comply with the *GSP* and the renewal requirements (or conditions met after rectification). Where the requirements are still not met after rectification, the license shall not be renewed.

During the prevention & control of the COVID-19 epidemic, relatively flexible regulatory measures can be taken, where necessary, for registration items of renewals and alterations. Where the enterprise cannot complete the application dossiers and on-site inspection preparations on time due to the epidemic situation, the validity period of its Drug Distribution License may be extended up to 90 days after the local epidemic prevention and control emergency response is lifted. Where the application for alterations of Drug Distribution License requires on-site inspection, the method of Informing & Pledging may be adopted. After the applicant submitted the application for alteration and commitment for GSP compliance, drug regulatory department shall handle the relevant licensing matters as a first step, and then complete the on-site inspection within 90 days after the local emergency response for epidemic prevention & control is lifted.

4. Where a drug distribution enterprise is subject to operation suspension since its *GSP Certificate* are cancelled or withdrawn due to GSP violations prior to December 1, 2019, it shall rectify the violations within the time limit required by the previous administrative measures. After the rectifications are in place, the

国家药品监督管理局发布《关于当前药品经营监督管理有关事宜的通告》

2020年4月3日，国家药品监督管理局发布《关于当前药品经营监督管理有关事宜的通告》，内容如下：

2019年12月1日，新修订的《中华人民共和国药品管理法》（以下简称《药品管理法》）实施，相关配套部门规章正在制定过程中。为贯彻落实《药品管理法》有关要求，进一步明确和规范药品经营环节监督管理工作，现将有关事宜通告如下：

一、新修订的《药品管理法》施行以来，在相关配套部门规章发布前，《药品经营许可证管理办法》（原国家食品药品监督管理局局令第6号）和《药品流通监督管理办法》（原国家食品药品监督管理局局令第26号）继续有效，其中规定与《药品管理法》不一致的，按照《药品管理法》执行。

二、新开办药品经营企业申请核发药品经营许可证的，药品监督管理部门可将筹建和验收程序合并执行，按照《药品经营质量管理规范》及现场检查指导原则等有关要求，对申办企业组织检查。符合要求的，发给药品经营许可证。

三、药品经营企业申请换发药品经营许可证的，药品监督管理部门按照换证工作程序和开办有关要求进行审查，符合《药品经营质量管理规范》和换发要求（或经整改后符合换发要求）的，予以换证；经整改后，仍不符合要求的，不予换证。

新冠肺炎疫情防控期间，药品经营许可证到期需要申请换发或变更许可事项的，可根据实际情况采取相对灵活的监管措施。如因疫情原因，企业无法按时完成申请材料和现场检查准备等工作的，其药品经营许可证的有效期可延长，最长可顺延至当地疫情防控应急响应解除后90日。药品经营许可证申请变更、需要现场检查的，可以采取告知承诺的方式，药品监督管理部门在企业提交变更申请和符合《药品经营质量管理规范》的承诺后，先行办理有关许可事项变更，在当地疫情防控应急响应解除后90日内完成现场检查。

四、2019年12月1日前，药品经营企业因违反《药品经营质量管理规范》而被撤销或收回《药品经营质量管理规范认证证书》暂停经营的，应当按照前期行政处理措施的要求时限整改。整改到位后，由药品经营企业提出申请，经药品监督管理部门审查，符合要求

enterprise can apply for resumption of operation, and resume business activities where conditions are met after review by drug administration departments; if rectifications failed to be made within the time limit, Article 126 of the *Drug Administration Law* shall apply.

5. Drug Marketing Authorization Holders shall abide by the provisions of Article 34 of the *Drug Administration Law* while selling their drugs that have obtained drug registration certificates. Pursuant to the *Reply on Issues Pertaining to Drug Production and Circulation in the Pilot of Drug Marketing Authorization Holders System* (NMPA Department of Drug Supervision Letter No. 25 [2018]), for consignment sales contract signed by MAH (Marketing Authorization Holder) and entrusted drug manufacturer prior to December 1, 2019, the entrusted manufacturer may sustain drug sales within the contract period but not beyond (in principle, the MAH-entrusted drug manufacturer's sales shall Not exceed December 31, 2022). As per the *Drug Administration Law*, after December 1, 2019, drug MAH shall not sign consignment sales contracts with entrusted drug manufacturers, and shall be ordered to make corrections within a time limit if they do so; if the MAH fails to correct the breach within a prescribed period of time, Article 115 of the *Drug Administration Law* shall apply.
6. Drug MAHs, manufacturers, distributors and user units should follow the *NMPA Guiding Opinions on the Construction of Drug Information Traceability System* (NMPA Department of Drug Supervision (2018) No. 35) and the NMPA-formulated unified standards and specifications, actively carry out the construction of drug information traceability system, and implement whole-process traceability by categories and stages in accordance with the subsequent work deployment of the NMPA. (April 3, 2020)

的方可继续开展经营活动；逾期不改正的，按照《药品管理法》第一百二十六条处理。

五、药品上市许可持有人销售其取得药品注册证书的药品，应当按照《药品管理法》第三十四条规定开展相关活动。依据《关于药品上市许可持有人试点工作药品生产流通有关事宜的批复》（国药监函〔2018〕25号）有关规定，在2019年12月1日前，药品上市许可持有人与受托药品生产企业已签订的委托销售合同，在合同期间内受托药品生产企业可继续销售药品，合同到期后不得继续委托药品生产企业销售药品（原则上，药品上市许可持有人委托药品生产企业销售药品不得超过2022年12月31日）。根据《药品管理法》规定，2019年12月1日后，药品上市许可持有人不得与受托药品生产企业签订委托销售合同，签订合同销售的，责令限期整改；逾期不改正的，依据《药品管理法》第一百一十五条处理。

六、药品上市许可持有人、生产企业、经营企业和使用单位应当根据《国家药监局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）以及国家药监局统一制定的标准和规范，主动开展药品信息化追溯体系建设，并按照后续国家药监局的工作部署，分类别、分阶段实施全过程可追溯。(2020-04-03)

NMPA Announcement on Issues Pertaining to the Implementation of the *Provisions for Drug Registration*

On March 31, 2020, NMPA issued the Announcement on Issues Pertaining to the Implementation of the *Provisions for Drug Registration* (No. 46 of 2020), which reads as follows:

The *Provisions for Drug Registration* (SAMR Order No. 27) (hereinafter referred to as the *Provisions*) has been promulgated by the State Administration for Market Regulation, and shall enter into force as from July 1, 2020. For better implementation of the new *Provisions* and their smooth transition and connection with the original *Provisions*, relevant matters are hereby announced:

1. After the release of the new *Provisions*, the normative documents and technical guidelines related to the new *Provisions* (hereinafter collectively referred to as the new *Provisions* and related documents) will be issued as per procedures. New stipulations and requirements made in the new *Provisions* shall prevail; and otherwise, the existing relevant stipulations and requirements shall apply.

For working procedures related to drug registration application & acceptance, review & approval, if no adjustments have been made by the new *Provisions* and related documents, the existing relevant stipulations shall apply.

2. Since the newly revised *Drug Administration Law* took effect, drugs approved for marketing will be issued

国家药品监督管理局发布关于实施《药品注册管理办法》有关事宜的公告

2020年3月31日，国家药品监督管理局关于实施《药品注册管理办法》有关事宜的公告（2020年第46号），内容如下：

《药品注册管理办法》（国家市场监督管理总局令第27号）（以下简称《办法》）已由国家市场监督管理总局发布，自2020年7月1日起施行。为做好新《办法》实施工作，保证新《办法》与原《办法》的顺利过渡和衔接，现将有关事宜公告如下：

一、新《办法》发布后，与新《办法》相关的规范性文件、技术指导原则等（以下简称新《办法》及其相关文件）将按程序陆续发布。新《办法》及其相关文件已作出规定和要求的，从其规定；无新规定和要求的，按照现行的有关规定和要求执行。

药品注册申请受理、审评和审批的有关工作程序，新《办法》及其相关文件尚未作

with drug registration certificates and attachments, and the New Drug Certificate shall no longer be issued. The drug registration certificate contains information such as the Marketing Authorization Holder and the manufacturer, together with the approved production process, quality standards, package inserts and labels. The approved chemical APIs shall be issued with the approval notification and the approved production process, quality standards and labels.

3. Before the implementation of the new *Provisions*, the submission of dossiers for drug registration application by MAH in the form of entrusted production shall follow the relevant provisions of the *Pilot Plan on Drug Marketing Authorization Holder System*; after the implementation of the new Provisions, the submission of application dossiers shall follow the newly released requirements.

4. For applications for drug marketing accepted after the new *Provisions* go into effect, the applicant shall obtain the corresponding drug production license beforehand; for applications for drug marketing accepted before the implementation of the new *Provisions* and approved after the implementation, the applicant shall obtain the corresponding drug production license before approval (If the drug manufacturing enterprise is the applicant, the drug production license shall be provided when the application for drug marketing is being accepted) .

During the period from the MAH pilot to the starting of the new Provisions, MAH with marketing approval acquired via entrusted production shall apply for drug production licensing to drug regulatory departments of their corresponding provinces, autonomous regions, and municipalities in accordance with the relevant provisions of the *Provisions for the Supervision and Administration of Drug Production*.

5. Drug registration applications accepted before the implementation of the new *Provisions* shall be reviewed and approved in accordance with the original drug registration classification and procedures. Pharmaceutical professional & technical institutions such as the National Institute for Food and Drug Control, the Chinese Pharmacopoeia Commission, the Center for Drug Evaluation, and the Center for Food and Drug Inspection should carry out relevant work on the premise of ensuring drug safety in accordance with the principles of legal compliance, fairness & equity, and benefiting the counterparty. The review, verification, inspection, approval of generic names and other tasks shall be handled in a timely manner. In principle, the follow-up work will be arranged in accordance with the chronological order of acceptance. Applicants can also choose to withdraw the original application, and apply anew per the newly implemented *Provisions*.

6. The scope and procedures of prioritized review & approval shall fit the following provisions:

(1) Drug registration applications accepted before the issuance of the new *Provisions* shall be implemented in accordance with the scope and procedures stipulated in the *Opinions on Fueling Pharmaceutical Innovation via Prioritized Review & Approval* (CFDA Department of Drug and Cosmetics Supervision [2017] No. 126) .

(2) Drug registration applications accepted between the issuance and the implementation of the new *Provisions* shall be handled in accordance with the scope stipulated in the new *Provisions* and the *Opinions on Encouraging Priority Review and Examination and procedures prescribed in the Opinions on Fueling Pharmaceutical Innovation via Prioritized Review & Approval* (CFDA Department of Drug and Cosmetics Supervision [2017] No. 126) .

(3) Drug registration applications accepted after the implementation of the new *Provisions* shall be executed in accordance with the scope and procedures prescribed by the new *Provisions*.

7. Drugs approved with conditions before the implementation of the new *Provisions* shall follow the provisions in Article 78

调整的，按照现行规定执行。

二、新修订《药品管理法》实施之日起，批准上市的药品发给药品注册证书及附件，不再发给新药证书。药品注册证书中载明上市许可持有人、生产企业等信息，同时附经核准的生产工艺、质量标准、说明书和标签。批准的化学原料药发给化学原料药批准通知书及核准后的生产工艺、质量标准和标签。

三、新《办法》实施前，以委托生产形式申请成为上市许可持有人的药品注册申请，按照《药品上市许可持有人制度试点方案》的有关规定提交相关申报资料；新《办法》实施后，按新发布的申报资料要求提交相关申报资料。

四、新《办法》实施后受理的药品上市许可申请，申请人应当在受理前取得相应的药品生产许可证；新《办法》实施前受理、实施后批准的药品上市许可申请，申请人应当在批准前取得相应的药品生产许可证（药品生产企业作为申请人的，在药品上市许可申请受理时提供药品生产许可证）。

上市许可持有人试点期间至新《办法》实施前，以委托生产形式获得批准上市的，其上市许可持有人应当按照《药品生产监督管理办法》实施的相关规定向所在地省、自治区、直辖市药品监督管理部门申请办理药品生产许可证。

五、新《办法》实施前受理的药品注册申请，按照原药品注册分类和程序审评审批。中检院、药典委、药品审评中心、药品核查中心等药品专业技术机构应当按照合法合规、公平公正、有利于相对人的原则，在保证药品安全的前提下开展相关工作，及时处理相关的审评、核查、检验、通用名称核准等各项工作，原则上按照受理时间顺序安排后续工作。申请人也可以选择撤回原申请，新《办法》实施后重新按照新《办法》的规定申报。

六、优先审评审批的范围和程序按以下规定执行：

（一）新《办法》发布前受理的药品注册申请，按照《关于鼓励药品创新实行优先审评审批的意见》（食药监药化管〔2017〕126号）规定的范围和程序执行。

（二）新《办法》发布至实施前受理的药品注册申请，按照新《办法》规定的范围和《关于鼓励药品创新实行优先审评审批的意见》（食药监药化管〔2017〕126号）规定的程序执行。

（三）新《办法》实施后受理的药品注册申请，按照新《办法》规定的范围和程序执行。

of the newly revised *Drug Administration Law* concerning post-marketing management of conditionally approved drugs.

8. For drugs manufactured overseas that are approved before the implementation of the new *Provisions*, the drug approval number shall be stated in the drug registration certificate as required by the new *Provisions*. The drug approval number of domestic sub-packages of drugs manufactured overseas shall be, invariably, identical with that on the bulk packaging.

9. For clinical trials of drugs that have been approved before the implementation of the new *Provisions*, the drug clinical trial license of those that have not been started within three years from the date of approval (taking the signing of informed consent of the subjects as the starting point) will automatically lapse.

10. From the date of promulgation of the new *Provisions*, the safety information related reports during the clinical trials of drugs shall be abide by the new *Provisions* and existing regulations.

11. For drugs approved before the implementation of the newly revised *Drug Administration Law*, MAH shall follow Article 49 of the newly revised Law and the *NMPA Announcement on Issues Pertaining to the Implementation of the Drug Administration's Law (No. 103 of 2019)* and update relevant MAH information in the package inserts and labels. Drugs produced in-country shall be subject to record filing by drug regulatory departments of corresponding provinces, autonomous regions and municipalities directly under the Central Government, while drugs produced overseas shall be filed at CDE. Drugs manufactured before December 1, 2020 can keep the existing printed package inserts and labels. The package inserts and labels of marketed drugs can continue to be used within the period of drug validity. If otherwise required by NMPA on revising package inserts and labels, the NMPA requirements shall prevail.

12. Drug administration departments at all levels should conscientiously implement the new Provisions, strengthen the corresponding promotion and training programs, pay attention to understand the important situations and problems encountered in implementation, and communicate and feedback in time to NMPA, who has set up a Column for *Provisions for Drug Registration* on the webpage to promptly summarize and release relevant documents and policy interpretations.

(March 31, 2020)

七、新《办法》实施前附条件批准的药品，应当按照新修订《药品管理法》第七十八条有关附条件批准药品上市后管理的规定执行。

八、新《办法》实施前批准的境外生产药品，在药品再注册时，按新《办法》要求在药品注册证书中载明药品批准文号。境外生产药品境内分包装统一使用该药品大包装的药品批准文号。

九、新《办法》实施前已批准的药物临床试验，自批准之日起，三年内仍未启动的（以受试者签署知情同意书为启动点），该药物临床试验许可自行失效。

十、自新《办法》发布之日起，药物临床试验期间安全性信息相关报告按照新《办法》及现有规定执行。

十一、新修订《药品管理法》实施前批准的药品，上市许可持有人应当按照新修订《药品管理法》第四十九条和《国家药监局关于贯彻实施〈中华人民共和国药品管理法〉有关事项的公告》（2019年第103号）关于上市许可持有人制度的有关规定更新说明书和标签中上市许可持有人的相关信息，境内生产药品在上市许可持有人所在地省、自治区、直辖市药品监督管理部门备案，境外生产药品在药品审评中心备案。2020年12月1日前生产的药品可以继续使用已印制的现有版本的说明书和标签。已上市销售药品的说明书和标签可以在药品有效期内继续使用。国家药品监督管理局对说明书和标签修订另有要求的除外。

十二、各级药品监督管理部门要认真贯彻执行新《办法》，加强对新《办法》的宣贯和培训，并注意了解新《办法》执行过程中遇到的重要情况和问题，及时沟通和向国家药品监督管理局反馈。国家药品监督管理局在网站设置《药品注册管理办法》栏目，及时汇总发布相关文件和政策解读。（2020-03-31）

NMPA Issued the Announcement on Issues Pertaining to the Implementation of the Newly Revised *Provisions for the Supervision and Administration of Drug Production*

On March 31, 2020, NMPA issued the Announcement on Issues Pertaining to the Implementation of the Newly Revised *Provisions for the Supervision and Administration of Drug Production* (No. 47 of 2020), which reads as follows:

The *Provisions for the Supervision and Administration of Drug Production* (SAMR Order No. 28, hereinafter referred to as the *Production Provisions*) has been promulgated and will come into force on July 1, 2020. For better supervision of drug

国家药品监督管理局发布关于实施新修订《药品生产监督管理办法》有关事项的公告

2020年3月31日，国家药品监督管理局发布关于实施新修订《药品生产监督管理办法》有关事项的公告（2020年第47号），内容如下：

《药品生产监督管理办法》（国家市场监督管理总局令第28号，以下简称《生产办

production, NMPA hereby announces the relevant matters as follows:

1. From July 1, 2020, applicants engaged in the production of preparations, APIs, and TCM slices should follow the relevant provisions of the *Production Provisions* while applying new for drug production licenses.

Applications for drug production licenses that have been accepted before July 1, 2020 but not yet approved afterwards shall be processed in accordance with the relevant provisions of the new *Production Provisions*.

The standards for on-site inspection and acceptance of production licenses shall comply with the relevant provisions of the *Drug Administration Law of the People's Republic of China* and its implementation regulations, and the relevant regulations of the *Good Manufacturing Practice for Drugs*. The scope of the *Drug Manufacturing Certificate (License)* shall specify the dosage form in the originals, and the workshop and production line in the copies.

2. The current *Drug Manufacturing Certificate* continues to be valid within the validity period. After the implementation of the *Production Provisions*, manufacturers' applications for alterations, renewal and re-issuance shall be reviewed in accordance with the relevant *Production Provisions*. While requirements are met, a new *Drug Manufacturing Certificate* shall be issued. The original validity period of alteration and reissuance remains unchanged, and the validity period of renewal is calculated from the current date of issuance.

3. Where the holders of drug marketing authorization (hereinafter referred to as *MAH*) who have obtained the *Drug Manufacturing Certificate* entrust the production of preparations, the provisions of Article 16 of the *Production Provisions* concerning changes to the production address or production scope shall apply. The company name, product name, approval number, validity period and other relevant changes of the entrusting parties shall be clearly stated in the copy of the *Drug Manufacturing Certificate*.

Where both entrusting parties are in the same province, the MAH shall submit relevant application dossiers to the local provincial drug regulatory authority, and the trustee shall cooperate with the holder to provide relevant materials. The provincial drug administration department shall review the application dossiers submitted by the holder, and conduct on-site inspections of the workshops and production lines where the trustee produces drugs, and make a decision for MAH to change production address, or production scope of the holder.

Where the entrusting parties are not in the same province, the trustee shall pass the on-site inspection of the drug production workshop and production line through the local provincial drug administration department, and cooperate with the holder to provide relevant application dossiers. The provincial drug administration department where the holder is located shall review the application dossiers submitted by the holder and make a decision to change the production address or production scope in accordance with the on-site inspection conclusion issued by the provincial department where the trustee is located.

Where the workshops or production lines involved in the entrusted production have not passed the compliance inspection of the Good Manufacturing Practice for Drugs drug production quality management standards (hereinafter referred to as *GMP compliance inspection*), the local provincial drug administration department should conduct a GMP compliance inspection.

4. The original approval documents for drug consignment production shall continue to be valid within the validity period. Upon implementation of the *Production Provisions*, if the Drug Manufacturing

法》）已发布，自2020年7月1日起施行。为进一步做好药品生产监管工作，国家药品监督管理局现将有关事项公告如下：

一、自2020年7月1日起，从事制剂、原料药、中药饮片生产活动的申请人，新申请药品生产许可，应当按照《生产办法》有关规定办理。

在2020年7月1日前，已受理但尚未批准的药品生产许可申请，在《生产办法》施行后，应当按照《生产办法》有关规定进行办理。

生产许可现场检查验收标准应当符合《中华人民共和国药品管理法》及实施条例有关规定和药品生产质量管理规范相关要求。《药品生产许可证》许可范围在正本应当载明剂型，在副本应当载明车间和生产线。

二、现有《药品生产许可证》在有效期内继续有效。《生产办法》施行后，对于药品生产企业申请变更、重新发证、补发等的，应当按照《生产办法》有关要求进行审查，符合规定的，发给新的《药品生产许可证》。变更、补发的原有效期不变，重新发证的有效期自发证之日起计算。

三、已取得《药品生产许可证》的药品上市许可持有人（以下称“持有人”）委托生产制剂的，按照《生产办法》第十六条有关变更生产地址或者生产范围的规定办理，委托双方的企业名称、品种名称、批准文号、有效期等有关变更情况，应当在《药品生产许可证》副本中载明。

委托双方在同一个省的，持有人应当向所在地省级药品监管部门提交相关申请材料，受托方应当配合持有人提供相关材料。省级药品监管部门应当对持有人提交的申请材料进行审查，并对受托方生产药品的车间和生产线开展现场检查，作出持有人变更生产地址或者生产范围的决定。

委托双方不在同一个省的，受托方应当通过所在地省级药品监管部门对受托方生产药品的车间和生产线的现场检查，配合持有人提供相关申请材料。持有人所在地省级药品监管部门应当对持有人提交的申请材料进行审查，并结合受托方所在地省级药品监管部门出具的现场检查结论，作出持有人变更生产地址或者生产范围的决定。

委托生产涉及的车间或者生产线没有经过药品生产质量管理规范符合性检查（以下简称“GMP符合性检查”），所在地省级药品监管部门应当进行GMP符合性检查。

四、原已经办理药品委托生产批件的，在有效期内继续有效。《生产办法》实施后，委托双方任何一方的《药品生产许可证》到期、变更、重新审查发证、补发的，

Certificate of either party is expired, changed, re-examined for reissuance or reissued, or the drug consignment production approval expired, the original entrusted production shall be terminated; and if the entrusted production shall continue, it shall be handled as per the Production Provisions concerning the change of production address and production scope and the requirements of this announcement. Approval documents for drug consignment production will no longer be issued separately.

5. For a manufacturer who obtains officially the *Drug Manufacturing Certificate* before July 1, 2020, and whose workshop or production line has not undergone GMP compliance inspection, it shall conduct GMP compliance inspection in accordance with the *Production Provisions*.
6. If the holder entrusts the production of a preparation, it shall sign with a qualified pharmaceutical manufacturer an entrustment agreement and a quality assurance agreement, the contents of which shall comply with the relevant laws and regulations. After NMPA releases the guidelines for the quality agreement on drug consignment production, both parties to the consignment shall complete and sign the entrustment agreement and quality agreement as required.
7. From the MAH pilot period to the starting of the newly revised *Provisions for Drug Registration*, the holders with marketing approval by entrusted production should apply for Drug Manufacturing Certificate to the local provincial drug administration department before July 1, 2020. The drug regulatory authorities at all levels shall, in accordance with the provisions of the MAH inspection procedures and key points, and their responsibilities, strengthen the supervision and inspection of the registration, production, operation and other links.
8. Drug administration departments at all levels should strengthen leadership, make overall arrangements, conduct effective publicizing and training concerning the *Production Provisions* in light of the actual work in the administrative region. It is necessary to fully implement the *Four Strictest* requirements of drug administration, strictly implement the laws and regulations, and reinforce the supervision of production links in accordance with the principle of territorial supervision, beef up cross-provincial production supervision and information notification, and make overall arrangements for 2020 *Drug Manufacturing Certificate* re-examinations, renewals and reissuances, to ensure that there is no reduction in administration efforts, standards, and continuous supervision, to ensure the quality and safety of medicines.
9. The *Production Provisions* and the relevant tables involved in this Announcement are shown in the attachment. Major problems encountered in the work shall be reported to NMPA in a timely manner. (March 31, 2020)

或者药品委托生产批件到期的，原委托生产应当终止，需要继续委托生产的，应当按照《生产办法》有关生产地址和生产范围变更的规定以及本公告的要求办理。药品委托生产不再单独发放药品委托生产批件。

五、2020年7月1日前，已依法取得《药品生产许可证》，且其车间或者生产线未进行GMP符合性检查的，应当按照《生产办法》规定进行GMP符合性检查。

六、持有人委托生产制剂的，应当与符合条件的药品生产企业签订委托协议和质量协议，委托协议和质量协议的内容应当符合有关法律法规规定。国家药监局发布药品委托生产质量协议指南后，委托双方应当按照要求对委托协议和质量协议进行完善和补充签订。

七、持有人试点期间至新修订《药品注册管理办法》实施前，以委托生产形式获得批准上市的，其持有人应在2020年7月1日前向所在地省级药品监管部门申请办理《药品生产许可证》。各级药品监管部门应当按照药品上市许可持有人检查工作程序及检查要点的规定，依职责加强持有人在注册、生产、经营等环节的监督检查。

八、各级药品监督管理部门要加强领导、统筹部署，结合本行政区域的工作实际，做好《生产办法》的宣贯和培训。要全面贯彻药品监管“四个最严”要求，严格落实药品管理法律法规规章等规定，按照属地监管原则，加大生产环节的监管力度，加强跨省委托生产监管和信息通报，统筹安排2020年《药品生产许可证》重新审查发证工作，确保监管力度不减、标准不降、监管不断，保证药品质量安全。

九、《生产办法》和本公告中涉及的相关表格见附件。工作中遇到的重大问题，应当及时报告国家药监局。 (2020-03-31)

Medical Devices

NMPA and NHC Issued *Regulations for Administration of Medical Device Extended Clinical Trials (Interim)*

To implement the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices*, and support the scalable clinical trials of medical devices, NMPA has, in conjunction with NHC formulated and released on March 20, 2020 the *Regulations for Administration of Medical Device Extended Clinical Trials (Interim)*.

(March 20, 2020)

医疗器械

国家药品监督管理局 国家卫生健康委发布《医疗器械拓展性临床试验管理规定（试行）》

为贯彻落实中共中央办公厅、国务院办公厅《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》，支持医疗器械拓展性临床试验工作，国家药品监督管理局会同国家卫生健康委员会制定了《医疗器械拓展性临床试验管理规定（试行）》，于2020年3月20日发布。 (2020-03-20)

Medical device unique identification database shared externally

To implement the CPC Central Committee and the State Council's policies for reform of the pharmaceutical and healthcare system and the management of high-value medical consumables, NMPA and the National Health Commission jointly launched a pilot project for the Unique Device Identification System. According to the work deployment, the UDI database was officially launched on December 10, 2019, with database sharing function opened on March 31, 2020. It is available for the public, medical device manufacturers, medical institutions various parties in three ways: query, download, and interface.

(March 31, 2020)

医疗器械唯一标识数据库对外共享

为贯彻落实党中央、国务院医药卫生体制改革和治理高值医用耗材改革有关精神，国家药品监督管理局会同国家卫生健康委联合开展了医疗器械唯一标识系统试点工作。按照工作部署，2019年12月10日唯一标识数据库正式上线，2020年3月31日开放数据库共享功能，以查询、下载、接口对接等三种方式，供公众、医疗器械生产经营企业和医疗机构等各方查询使用。 (2020-03-31)

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。
• 电子版Newsletter阅览请登录网站http://www.ccfdie.org

China Center for Food and Drug International Exchange (CCFDIE)
中国食品药品国际交流中心
Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, P.R.C.
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编：100082
Tel: 010-8221 2866 Fax: 010-8221 2857
Email: ccfdie@ccfdie.org
Website: www.ccfdie.org

Servier (Tianjin) Pharmaceutical Co., Ltd.
施维雅（天津）制药有限公司
Address: 6 Floor, West Building, World Financial Center, No.1, East 3rd Ring Middle Road, Chaoyang District, 100020 Beijing, China
北京市朝阳区东三环中路1号环球金融中心西楼6层
邮编：100020
Tel: 010-6561 0341
Fax: 010-6561 0348
Website: www.servier.com.cn