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General Office of the State Council Issued the *Opinions on Establishing a Team of Professionalized & Specialized Drug Inspectors*

Recently, the General Office of the State Council issued the *Opinions on Establishing a Team of Professionalized & Specialized Drug Inspectors* (hereinafter referred to as Opinions).

The *Opinions* defines professional & specialized inspectors of drugs (incl. medical devices and cosmetics) as those who accredited by the drug regulatory authorities to conduct compliance verification and risk assessment on places and activities where the administrative counterparts engage in drug R&D and production, etc. The inspectors constitute an important supporting force for strengthening drug supervision and ensuring drug safety. Per the professionalization orientation and professional & technical requirements, by the end of 2020, the drug regulatory authorities of the State Council and the provincial levels shall have basically completed the construction of a system of professional & specialized drug inspectors. On this basis, it will take another three to five years to build and further improve a politically and professionally qualified, honest and efficient professional & specialized drug inspector team system with full-time inspectors as the mainstay and part-time inspectors as a supplement, basically satisfying the requirements for drug administration.

The *Opinions* proposes five policy measures. 1. Improve the institutions and mechanisms of drug inspection. Professional & specialized teams of drug inspectors shall be constructed at the national and provincial levels with reinforced institution construction, clarified division of powers, refined inspection requirements, and ameliorated coordination mechanism for inspections. 2. Ensure the staffing of inspectors. Reasonably determine the size of the team, standardize the staffing management, innovate the inspector management mechanism, and enrich the inspector team through multiple channels. 3. Strengthen the management of the inspectors. Professionalized & specialized drug inspectors shall be subject to hierarchical classification management with strict job access and employment conditions, and scientific and reasonable mechanisms for assessment & evaluation, promotion and demotion. 4. Continuously improve the ability and quality of inspectors. Strengthen inspector business training, encourage self-improvement, and innovate high-quality inspector training mode. 5. Establish an incentive and restraint mechanism. Broaden the professional development space of inspectors, improve the policy for inspectors to participate in the evaluation of corresponding professional titles, establish a guarantee mechanism for remuneration, and strengthen discipline and supervision.

(July 19, 2019)

国务院办公厅印发《关于建立职业化专业化药品检查员队伍的意见》

近日，国务院办公厅印发《关于建立职业化专业化药品检查员队伍的意见》（以下简称《意见》）。

《意见》提出，职业化专业化药品（含医疗器械、化妆品）检查员是指经药品监管部门认定，依法对管理相对人从事药品研制、生产等场所、活动进行合规确认和风险研判的人员，是加强药品监管、保障药品安全的重要支撑力量。要坚持职业化方向和专业性、技术性要求，到2020年底，国务院药品监管部门和省级药品监管部门基本完成职业化专业化药品检查员队伍制度体系建设。在此基础上，再用三到五年时间，构建起基本满足药品监管要求的职业化专业化药品检查员队伍体系，进一步完善以专职检查员为主体、兼职检查员为补充，政治过硬、素质优良、业务精湛、廉洁高效的检查员队伍。

《意见》提出了五方面政策措施。一是完善药品检查体制机制。构建国家、省两级职业化专业化药品检查员队伍，强化检查机构建设，明确检查事权划分，落实检查要求，完善检查工作协调机制。二是落实检查员配置。合理确定队伍规模，规范检查员编制管理，创新检查员管理机制，多渠道充实检查员队伍。三是加强检查员队伍管理。职业化专业化药品检查员实行分级分类管理，确立严格的岗位准入和任职条件，建立科学合理的考核评价与职级升降机制。四是不断提升检查员能力素质。强化检查员业务培训，鼓励检查员提升能力水平，创新高素质检查员培养模式。五是建立激励约束机制。拓宽检查员职业发展空间，完善检查员参加相应职称评审的政策，建立检查员薪酬待遇保障机制，强化纪律约束和监督。

(2019-07-19)

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NMPA Issued the *Announcement on Issues Pertaining to the Implementation of Drug Standards in the Consistency Evaluation of the Quality and Efficacy of Generic Drugs*

To promote the consistency evaluation of the quality and efficacy of generic drugs, and clarify the relationship between the registration standards of generic drugs and the national drug standards such as the Pharmacopoeia of the People's Republic of China, on August 2, 2019, NMPA issued the *Announcement on Issues Pertaining to the Implementation of Drug Standards in the Consistency Evaluation of the Quality and Efficacy of Generic Drugs*. (August 2, 2019)

国家药品监督管理局发布《关于仿制药质量和疗效一致性评价工作中药品标准执行有关事宜的公告》

为推进仿制药质量和疗效一致性评价工作，明确仿制药注册标准和《中华人民共和国药典》等国家药品标准的关系，2019年8月2日，国家药品监督管理局发布了《关于仿制药质量和疗效一致性评价工作中药品标准执行有关事宜的公告》。 (2019-08-02)

NMPA Issued the *Announcement on Cancellation of 16 Certification Items (Second Batch)*

As per the *Notice of the General Office of the State Council on Effective Clearance of Certification Items* (the State Council General Office [2018] No. 47), to further reduce redundant certification for the convenience of the people and service optimization, NMPA issued on July 24, 2019 the *Announcement on Cancellation of 16 Certification Items (Second Batch)*, the listed certification items shall be suspended from the date of promulgation. (July 24, 2019)

国家药品监督管理局发布《关于取消16项证明事项的公告（第二批）》

根据《国务院办公厅关于做好证明事项清理工作的通知》（国办发〔2018〕47号）要求，为进一步减证便民、优化服务，2019年7月24日，国家药品监督管理局发布《关于取消16项证明事项的公告（第二批）》，自发布之日起，所列证明事项停止执行。 (2019-07-24)

NMPA Issued the *Announcement on Issues Concerning the Further Improvement of Drug-related Associated Review & Approval and Supervision*

As per the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review & Approval System to Encourage Innovation in Drugs and Medical Devices* (General Office [2017] No. 42), and the *Announcement on Adjusting the Review & Approval Items of APIs, Pharmaceutical Excipients and Packaging Materials* (Announcement No. 146 of 2017) issued by the former CFDA, on July 16, 2019, NMPA issued the *Announcement on Issues Concerning the Further Improvement of Drug-related Associated Review & Approval and Supervision*, to further clarify the administrative details for associated review & approval and supervision of APIs, pharmaceutical excipients, packaging materials and containers in direct contact with pharmaceuticals (hereinafter referred to as AEP: APIs+ excipients + packaging) with drugs/preparations.

I. Overall requirements

(1) The use of AEP must comply with the medicinal requirements, mainly referring to the quality, safety and function of AEP should meet the needs of the pharmaceutical preparation. The review & approval of AEP and drug/preparation associated registration shall be registered on the registration platform by AEP registrant, and the drug/preparation registration applicant shall associate the data with the

国家药品监督管理局发布《关于进一步完善药品关联审评审批和监管工作有关事宜的公告》

为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》（厅字〔2017〕42号），原食品药品监管总局发布了《关于调整原料药、药用辅料和药包材审评审批事项的公告》（2017年第146号），2019年7月16日，国家药品监督管理局发布《关于进一步完善药品关联审评审批和监管工作有关事宜的公告》，就原料药、药用辅料、直接接触药品的包装材料和容器（以下简称原辅包）与药品制剂关联审评审批和监管有关事宜进行了进一步明确。

一、总体要求

（一）原辅包的使用必须符合药用要求，主要是指原辅包的质量、安全及功能应该满足药品制剂的需要。原辅包与药品制剂

platform registration data when submitting the registration application; for AEPs that cannot be registered on the platform for special reasons, it is also possible for drug/preparation registration applicants to provide the AEP research dossiers together with the application for drug/preparation registration.

(2) AEP registrant is responsible for maintaining the registration information of the registration platform, and for the authenticity and completeness of the registration information. AEP supplier, as AEP registrant, shall register the product voluntarily. The overseas AEP suppliers may be registered by their resident representative offices in China, or entrusted Chinese agencies. The registration information shall be in Chinese, and the overseas AEP supplier and agency shall be jointly responsible for the authenticity and completeness of the registration information.

(3) When applying for registration of a drug/preparation, the applicant must provide the AEP registration number and the authorization letter of AEP registrant.

(4) The applicant for drug/preparation registration or the Marketing Authorization Holder bears the principal responsibility for drug quality. According to the relevant requirements for drug registration and post-marketing production management, the quality management system of AEP supplier shall be audited to ensure compliance with the requirements of drug use.

(5) The regulatory department shall be responsible for the confidentiality of the technical information submitted by AEP registrant, as well as the technical information of the registration platform. The registration platform shall disclose only the registered variety's registration status indicator (A or I), registration number, variety name, company/agency name, production address, the original drug approval number (if any), the validity period of the original approval document (if any), product source, specification, update date and other necessary information.

II. Product registration management

(6) AEP registrant shall register on the platform per the technical requirements of the registration dossiers, and obtain the registration number. APIs should, prior to registration, obtain the *Drug Manufacturing Certificate* within the corresponding production scope, and register in accordance with the *Announcement on Promulgating the Requirements for Application Dossiers of Chemicals in New Registration Classifications (Interim)* (CFDA Announcement No. 80 of 2016); pharmaceutical excipients and pharmaceutical packaging materials shall be registered per the data requirements of Annex 1 and Annex 2 of this Announcement. The technical requirements for registration dossiers shall be continuously improved according to industrial development and scientific and technological progress, and updated and announced in due course by CDE of NMPA (hereinafter referred to as CDE).

(7) The application for registration of the drug/preparation shall be associated with the registered AEP. Where the drug/preparation is approved, it indicates that its associated AEP has also passed the technical review, and marked as *A* on the registration platform; where the technical review failed or the association is unestablished, the identifier shall be *I*.

(8) Except for AEPs phased out, cancelled, or prohibited by the state from being used, AEP that meets the following conditions shall be transferred to the registration platform by CDE and the registration number shall be given, and the registration status shall be marked as *A*:

1. APIs with an expiration date of the approval/proof document no earlier than November 27, 2017;
2. APIs that have been accepted and

关联审评审批由原辅包登记人在登记平台上登记，药品制剂注册申请人提交注册申请时与平台登记资料进行关联；因特殊原因无法在平台登记的原辅包，也可在药品制剂注册申请时，由药品制剂注册申请人一并提供原辅包研究资料。

（二）原辅包登记人负责维护登记平台的登记信息，并对登记资料的真实性和完整性负责。境内原辅包供应商作为原辅包登记人应当对所持有的产品自行登记。境外原辅包供应商可由常驻中国代表机构或委托中国代理机构进行登记，登记资料应当为中文，境外原辅包供应商和代理机构共同对登记资料的真实性和完整性负责。

（三）药品制剂注册申请人申报药品注册申请时，需提供原辅包登记号和原辅包登记人的使用授权书。

（四）药品制剂注册申请人或药品上市许可持有人对药品质量承担主体责任，根据药品注册管理和上市后生产管理的有关要求，对原辅包供应商质量管理体系进行审计，保证符合药用要求。

（五）监管部门对原辅包登记人提交的技术资料负有保密责任，对登记平台的技术信息保密，登记平台只公开登记品种的登记状态标识（A或I）、登记号、品种名称、企业名称（代理机构名称）、企业生产地址、原药品批准文号（如有），原批准证明文件有效期（如有），产品来源、规格、更新日期和其他必要的信息。

二、产品登记管理

（六）原辅包登记人按照登记资料技术要求在平台登记，获得登记号。其中，原料药在登记前应取得相应生产范围的《药品生产许可证》，并按照原食品药品监管总局《关于发布化学药品新注册分类申报资料要求（试行）的通告》（2016年第80号）要求进行登记；药用辅料和药包材登记按照本公告附件1、附件2的资料要求进行登记。登记资料技术要求根据产业发展和科学技术进步不断完善，由国家药品监督管理局药品审评中心（以下简称药审中心）适时更新公布。

（七）药品制剂注册申请与已登记原辅包进行关联，药品制剂获得批准时，即表明其关联的原辅包通过了技术审评，登记平台标识为“A”；未通过技术审评或尚未与制剂注册进行关联的标识为“I”。

（八）除国家公布禁止使用、淘汰或者注销的原辅包外，符合以下情形的原辅包由药审中心将相关信息转入登记平台并给予登记号，登记状态标识为“A”：

1. 批准证明文件有效期届满日不早于

completed for review and approval, including the application for technology transfer of APIs reviewed by the provincial administration in accordance with the CFDA Department of Drug Registration [2013] No. 38 Document;

3. Pharmaceutical excipients and pharmaceutical packaging materials whose applications have been accepted and completed for review;
4. Pharmaceutical excipients that once obtained approval documents;
5. Pharmaceutical packaging materials with an expiration date of the approval/proof document no earlier than August 10, 2016.

AEP registrant transferred to the registration platform shall submit the research materials on the platform per the requirements for registration dossiers stated herein, enrich the registration information, and submit the data consistency commitment letter (claiming that the technical data submitted by the registration platform is consistent with that of the registration approval).

(9) For APIs of generics or imported drug/preparation domestically marketed, after the registration of the API registrants, they may be subject to separate review and approval, and the registration status of the passed review & approval shall be marked as *A*, otherwise: *I*. The time limit and requirements for review and approval shall comply with the *Provisions for Drug Registration* and other relevant regulations.

(10) Pharmaceutical excipients with long-term usage in foods and medicines and recognized safety (see Annex 3 for details of the list) can do without registration, the applicants for registration of drug/preparation shall list the product list and basic information in the preparation application dossiers. However, where CDE considers it necessary during the review process of drug/preparation registration application, it may request the applicant to provide the corresponding technical information. The list of such medicinal excipients shall be updated by CDE in due course.

(11) Administrative licenses have been cancelled for pharmaceutical excipients and pharmaceutical packaging materials, thence no fees are charged for platform registration. APIs, however, are still subject to administrative licenses, and the relevant requirements for platform registration and technical review are implemented in accordance with current regulations and standards.

III. The use and management of AEP registration information

(12) Where the research materials of AEP registration platform cannot meet the needs in the associated review of application for registration of drug/preparation, CDE may require the applicant or the original registrant to supplement dossiers. The means of submission of supplementary information shall be specified by CDE in the notice for supplementary information.

(13) Where the API is marked as *A*, it indicates that the API has passed the review and approval. The APIs registrant can print the approval/proof document, quality standards and labels etc. via the registration platform voluntarily for GMP inspection and import customs clearance.

For APIs not registered on the platform and whose research materials are submitted together with the drug/preparation registration application dossiers, the regulatory department shall indicate the relevant APIs information in the drug/preparation approval document, which may be used for the GMP inspection of APIs and import customs clearance.

(14) The procedures and requirements of APIs manufacturers' application for GMP inspection shall comply with the relevant provisions of the current laws and regulations, and the registration information shall be updated on the registration platform

2017年11月27日的原料药；
2. 已受理并完成审评审批的原料药，含省局按照国食药监注〔2013〕38号文审评的原料药技术转让申请；
3. 已受理并完成审评的药用辅料和药包材；
4. 曾获得批准证明文件的药用辅料；
5. 批准证明文件有效期届满日不早于2016年8月10日的药包材。

转入登记平台的原辅包登记人应按照本公告登记资料要求在登记平台补充提交研究资料，完善登记信息，同时提交资料一致性承诺书（承诺登记平台提交的技术资料与注册批准技术资料一致）。

（九）仿制或进口境内已上市药品制剂所用的原料药，原料药登记人登记后，可进行单独审评审批，通过审评审批的登记状态标识为“A”，未通过审评审批的标识为“I”。审评审批时限和要求按照现行《药品注册管理办法》等有关规定执行。

（十）已在食品、药品中长期使用且安全性得到认可的药用辅料可不进行登记（名单详见附件3），由药品制剂注册申请人在制剂申报资料中列明产品清单和基本信息。但药审中心在药品制剂注册申请的审评过程中认为有必要的，可要求药品制剂注册申请人补充提供相应技术资料。该类药用辅料品种名单由药审中心适时更新公布。

（十一）药用辅料、药包材已取消行政许可，平台登记不收取费用。原料药仍为行政许可，平台登记技术审评相关要求按现行规定和标准执行。

三、原辅包登记信息的使用和管理

（十二）药品制剂注册申请关联审评时，原辅包登记平台研究资料不能满足审评需要的，药审中心可以要求药品制剂注册申请人或原辅包登记人进行补充。补充资料的报送途径由药审中心在发补通知中明确。

（十三）原料药标识为“A”的，表明原料药已通过审评审批。原料药登记人可以在登记平台自行打印批准证明文件、质量标准和标签等，用于办理GMP检查、进口通关等。

未进行平台登记而与药品制剂注册申报资料一并提交研究资料的原料药，监管部门在药品制剂批准证明文件中标注原料药相关信息，可用于办理原料药GMP检查、进口通关等。

（十四）原料药生产企业申请GMP检查程序及要求按照现行法律法规有关规定执行，通过药品GMP检查后应在登记平台更新登记信息。

after passing the drug GMP inspection.

(15) Where a technical change of APIs identified as *A* occurs, an application for change shall be submitted in accordance with the relevant provisions on the current drug registration management, and shall be implemented after approval. Other changes in APIs, changes in pharmaceutical excipients and pharmaceutical packaging materials should be updated in a timely manner on the registration platform and summarized in the previous year's annual report submitted in the first quarter of each year.

(16) Where any change arises for AEP, the AEP registrant shall initiate research on its own initiative, and promptly notify the relevant drug/preparation production enterprise (Drug Marketing Authorization Holders), update the registration information in a timely manner and specify it in the annual report.

After receiving the above notice, the drug/preparation manufacturer (Marketing Authorization Holder) shall promptly evaluate or study the impact of the corresponding change on the quality of the drug/preparation, if quality is affected, it shall file a supplementary application.

(17) Where the AEP and AEP supplier of marketed pharmaceutical preparations are subject to change, research shall be conducted following the *Technical Guidelines for Studies on the Alterations of Post-Marketed Chemicals (I), Technical Guidelines for Studies on the Production Process Alterations of Post-Marketed Chemicals*, and *Technical Guidelines for Studies on Alterations of Post-Marketed TCMs (I)*, as well as the relevant provisions on the current drug registration management.

(18) Where the overseas AEP supplier replaces the registration agency, it shall be changed after submitting relevant documents and materials, including: explanation of reasons for change, letter of entrustment by overseas AEP supplier along with its notarized document and its Chinese translation, copy of business license of new agency, document of foreign AEP supplier to cancel the entrustment relationship of the original agency along with its notarized document and Chinese Translation.

IV. Supervision and management

(19) The drug regulatory authorities of the provinces (autonomous regions and municipalities) shall, after the marketing of the APIs with the registration status marked *A*, conduct post-marketing management according to the drugs, and carry out drug GMP inspections.

(20) The drug regulatory authorities of the provinces (autonomous regions and municipalities) shall strengthen the supervision and inspection of drug/preparation enterprises (Drug Marketing Authorization Holder) within their respective administrative regions, supervise and urge drug/preparation enterprises (Drug Marketing Authorization Holder) to perform supplier audit responsibility for APIs, pharmaceutical excipients and pharmaceutical packaging materials.

For pharmaceutical excipients and pharmaceutical packaging materials manufacturers holding the *Drug Manufacturing Certificate*, they shall continue to be managed according to the original administrative requirements. After the *Certificate* expires, the site information shall be registered in accordance with the requirements of this Announcement.

(21) The drug regulatory authorities of all provinces (autonomous regions and municipalities) shall strengthen supervision, inspection and extension inspection of suppliers of pharmaceutical excipients and pharmaceutical packaging materials according to the registration information. Where quality problems are spotted in the production of pharmaceutical excipients and pharmaceutical packaging materials, they shall be investigated and dealt with in accordance with the laws and regulations in a timely manner, the corresponding drug/preparation manufacturers (drug Marketing Authorization Holders) shall no longer use the relevant products, and the marketed products shall be subject to evaluation and disposal. The extended inspection shall be organized by the provincial

（十五）标识为“A”的原料药发生技术变更的，按照现行药品注册管理有关规定提交变更申请，经批准后实施。原料药的其他变更、药用辅料和药包材的变更应及时在登记平台更新信息，并在每年第一季度提交的上一年年度报告中汇总。

（十六）原辅包发生变更时原辅包登记人应主动开展研究，并及时通知相关药品制剂生产企业（药品上市许可持有人），并及时更新登记资料，并在年报中体现。

药品制剂生产企业（药品上市许可持有人）接到上述通知后应及时就相应变更对药品制剂质量的影响情况进行评估或研究，属于影响药品制剂质量的，应报补充申请。

（十七）已上市药品制剂变更原辅包及原辅包供应商的，应按照《已上市化学药品变更研究技术指导原则（一）》《已上市化学药品生产工艺变更研究技术指导原则》《已上市中药变更研究技术指导原则（一）》及生物制品上市后变更研究相关指导原则等要求开展研究，并按照现行药品注册管理有关规定执行。

（十八）境外原辅包供应商更换登记代理机构的，提交相关文件资料后予以变更。包括：变更原因说明、境外原辅包供应商委托书、公证文书及其中文译本、新代理机构营业执照复印件、境外原辅包供应商解除原代理机构委托关系的文书、公证文书及其中文译本。

四、监督管理

（十九）各省（区、市）药品监督管理局对登记状态标识为“A”的原料药，按照药品进行上市后管理，并开展药品GMP检查。

（二十）各省（区、市）药品监督管理局应加强对本行政区域内药品制剂生产企业（药品上市许可持有人）的监督检查，督促药品制剂生产企业（药品上市许可持有人）履行原料药、药用辅料和药包材的供应商审计责任。

药用辅料和药包材生产企业具有《药品生产许可证》的，继续按原管理要求管理，许可证到期后按本公告要求登记场地信息。

（二十一）各省（区、市）药品监督管理局根据登记信息对药用辅料和药包材供应商加强监督检查和延伸检查。发现药用辅料和药包材生产存在质量问题的，应依法依规及时查处，并要求药品制剂生产企业（药品上市许可持有人）不得使用相关产品，并对已上市产品开展评估和处置。延伸检查应由药品制剂生产企业（药品上市许可持有人）所在地省局组织开展。药用辅料和药包材供

administration where the drug/preparation manufacturer (drug Marketing Authorization Holder) is located. The daily inspection of suppliers of pharmaceutical excipients and pharmaceutical packaging materials shall be organized by the local provincial administration for joint inspection.

On-site inspection of the production of pharmaceutical excipients shall be carried out in accordance with the *GMP for Pharmaceutical Excipients* (SFDA Department of Drug Supervision [2006] No. 120). The on-site production inspection of the pharmaceutical packaging materials shall follow the *General Rules for Production Site Inspection of Pharmaceutical Packaging Materials* attached to the *Measures for the Administration of Packaging Materials and Containers for Direct Contact with Medicines (Former SFDA Order No. 13)*. The drug regulatory authorities of various provinces (autonomous regions and municipalities) may further improve relevant technical specifications and inspection standards according to regulatory needs, and promote the steady improvement of the quality of excipients and pharmaceutical packaging materials.

NMPA shall revise the relevant inspection standards in due time according to the situation and needs of various provinces' supervision and inspection.

V. Others

(22) APIs, pharmaceutical excipients and pharmaceutical packaging materials developed, produced, imported and used within the territory of the People's Republic of China shall be applicable to the requirements of this Announcement.

(23) This Announcement shall come into force as of August 15, 2019. Where the original documents related to AEP are inconsistent with the requirements of this Announcement, this Announcement shall prevail. The *Announcement on the Release of Requirements for Application Dossiers of Pharmaceutical Packaging Materials and Pharmaceutical Excipients* (Interim) (Announcement No. 155, 2016) issued by the former CFDA, shall be repealed simultaneously

Annexes:

1. Requirements for registration of medical excipients (Interim)(omitted)
2. Requirements for registration of medical packaging materials (Interim) (omitted)
3. Catalogue of products that can be exempted from registration (2019 edition) (omitted)
4. Basic requirements for the annual report of medicinal raw materials, excipients and pharmaceutical packaging materials (omitted)

(July 16, 2019)

应商的日常检查由所在地省局组织开展联合检查。

药用辅料生产现场检查参照《药用辅料生产质量管理规范》（国药监安〔2006〕120号）开展检查，药包材生产现场检查参照《直接接触药品的包装材料和容器管理办法》（原国家食品药品监督管理局局令第13号）中所附《药包材生产现场考核通则》开展检查。各省（区、市）药品监督管理局可根据监管需要进一步完善相关技术规范和检查标准，促进辅料和药包材质量水平稳步提升。

国家药品监督管理局将根据各省监督检查开展情况和需要，适时修订相关检查标准。

五、其他

（二十二）在中华人民共和国境内研制、生产、进口和使用的原料药、药用辅料、药包材适用于本公告要求。

（二十三）本公告自2019年8月15日起实施。原发布的原辅包相关文件与本公告要求不一致的，以本公告为准。原食品药品监管总局发布的《关于发布药包材药用辅料申报资料要求（试行）的通告》（2016年第155号）同时废止。

附件：1. 药用辅料登记资料要求（试行）（略）
2. 药包材登记资料要求（试行）（略）
3. 可免登记的产品目录（2019年版）（略）
4. 药用原辅料、药包材年度报告基本要求（略）

(2019-07-16)

Medical Devices

NMPA Issued the *Notice on Expanding the Pilot of the Medical Device Registrant System*

As per the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review & Approval System to Encourage Innovation in Drugs and Medical Devices* (General Office [2017] No. 42), to accelerate the innovation and development of the medical device industry, on the basis of the early pilots of medical device registrant system in Shanghai, Guangdong and Tianjin Free Trade Zones, on August 1, 2019, NMPA issued the *Notice on Expanding the Pilot of the Medical Device Registrant System* (NMPA Department for Medical Device Registration [2019] No. 33, hereinafter referred to as the Notice, to further expand the pilot program of the medical device registrant system, and further accumulate experience for the full implementation of it.

The *Notice* stipulates the corresponding conditions and obligations for the registrants and the entrusted manufacturers

医疗器械

国家药品监督管理局发布《关于扩大医疗器械注册人制度试点工作的通知》

为深入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》（厅字〔2017〕42号）精神，加快推进医疗器械产业创新发展，在前期上海、广东、天津自贸区开展医疗器械注册人制度试点工作的基础上，2019年8月1日，国家药品监督管理局发布《关于扩大医疗器械注册人制度试点工作的通知》（国药监械注〔2019〕33号，以下简称《通知》），进一步扩大医疗器械注册人制度试点，为全面实施医疗器械注册人制度

participating in the pilot, clarifying that both parties should sign the entrustment contract and quality assurance agreement; it also stipulates the procedures for product registration, alterations and manufacturer license. At the same time, it is emphasized that drug regulatory authorities at all levels should strengthen supervision and management of registrants' performance of obligations such as guaranteeing quality of medical devices, market sales and services, monitoring and evaluation of adverse events of medical devices, and recall of medical devices, etc. (August 1, 2019)

进一步积累经验。

《通知》对参与试点工作的注册人和受托生产企业分别规定了相应的条件和义务责任，明确双方应当签订委托合同和质量协议，并对产品注册、变更和生产企业许可证办理程序进行了规定，同时强调各级药品监管部门应当加强对注册人履行保证医疗器械质量、上市销售与服务、医疗器械不良事件监测与评价、医疗器械召回等义务情况的监督管理。 (2019-08-01)

NMPA Issued the *Announcement on the Requirements for Filing Review of Registration Items of Medical Device Products (Interim)*

As per the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review & Approval System to Encourage Innovation in Drugs and Medical Devices* (General Office [2017] No. 42), in conjunction with the roll out of electronic application of medical device registration, according to the *Provisions for Medical Device Registration* (former CFDA Decree No. 4) and the requirements of other documents, NMPA organized the formulation of the *Requirements for Filing Review of Registration Items of Medical Device Products (Interim)*, which has been released on July 10, 2019, and shall enter into force as from September 1, 2019.

The NMPA Center for Medical Device Evaluation shall examine the dossiers of the corresponding applications in accordance with the requirements for filing review in the case-acceptance process, to judge the integrity, compliance and consistency of the application dossiers entering the technical review process. The filing review does not analyze the rationality and adequacy of product safety and effectiveness evaluation, and does not judge the product risk benefit ratio. It is applicable to applications such as medical device registration, licensing alterations, and clinical trial approval.

(July 10, 2019)

国家药品监督管理局发布《关于医疗器械产品注册项目立卷审查要求（试行）》等文件的通告》

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》（厅字〔2017〕42号），配合医疗器械注册电子申报工作的开展，根据《医疗器械注册管理办法》（原国家食品药品监督管理总局令第4号）等文件要求，国家药品监督管理局组织制定了《医疗器械产品注册项目立卷审查要求（试行）》等立卷审查要求，于2019年7月10日发布，自2019年9月1日起实施。

国家药品监督管理局医疗器械技术审评中心在受理环节按照立卷审查要求对相应申请的申报资料进行审查，对申报资料进入技术审评环节的完整性、合规性、一致性进行判断。立卷审查不对产品安全性、有效性评价的合理性、充分性进行分析，不对产品风险受益比进行判定。立卷审查适用于医疗器械注册、许可事项变更、临床试验审批等申请事项。 (2019-07-10)

NMPA Issued the *Announcement on the Requirements for Relevant Electronic Application Dossiers of Medical Devices*

Pursuant to the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review & Approval System to Encourage Innovation in Drugs and Medical Devices* (General Office [2017] No. 42), to orderly promote the electronic application of medical device registration, on July 10, 2019, NMPA issued the *Announcement on the Requirements for Relevant Electronic Application Dossiers of Medical Devices*, to regulate the submission of relevant dossiers.

(July 10, 2019)

国家药品监督管理局发布《关于医疗器械电子申报有关资料要求的通告》

为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》（厅字〔2017〕42号）的要求，有序推进医疗器械注册电子申报工作，2019年7月10日，国家药品监督管理局发布《关于医疗器械电子申报有关资料要求的通告》，就有关资料的提交提出了要求。 (2019-07-10)

NMPA Issued the *Announcement on Medical Device GMP Appendix: Independent Software*

To strengthen production supervision of independent software as medical devices and regulate its quality management, according to the *Regulations for the Supervision and Administration of Medical Devices* (State Council Order No. 680), and the *Administrative Measures for the Supervision of Medical Device Manufacturing* (CFDA Order No. 7), NMPA organized the drafting of and released on July 12, 2019 the *Medical Device GMP Appendix: Independent Software*.

This Appendix features special requirements for independent software medical device GMP. The independent software medical device production quality management system shall comply with the requirements of the *Medical Device GMP* and this Appendix. (July 12, 2019)

国家药品监督管理局发布《关于医疗器械生产质量管理规范附录独立软件的通告》

为加强独立软件类医疗器械生产监管，规范独立软件生产质量管理，根据《医疗器械监督管理条例》（国务院令680号）、《医疗器械生产监督管理办法》（国家食品药品监督管理总局令第7号），国家药品监督管理局组织起草了《医疗器械生产质量管理规范附录独立软件》，于2019年7月12日发布。

本附录是独立软件医疗器械生产质量管理规范的特殊要求。独立软件类医疗器械生产质量管理体系应当符合《医疗器械生产质量管理规范》及本附录的要求。(2019-07-12)

General Information

Debut of NMPA English Website

On July 18, 2019, the English website of NMPA was officially launched, marking another important measure for comprehensive promotion of drug regulatory information disclosure and public communication in the wake of the establishment of NMPA. At present, the English-version website has set up About NMPA, News, Laws & Regulations, Regulatory Information, Policies Interpretation, Popular Science, Drugs, Medical Devices, Cosmetics and other Columns that are basically in line with those of the Chinese website. NMPA will strive to achieve synchronous update of Chinese and English information henceforth, to timely transmit the information of China's supervision over drugs, medical devices and cosmetics to the world. (July 19, 2019)

综合信息

国家药品监督管理局英文网站上线

2019年7月18日，国家药品监督管理局英文网站正式上线，这是国家药品监督管理局组建后，全面推进药品监管信息公开、加强公众交流的又一重要举措。目前，英文版网站设置了机构简介、新闻动态、法规文件、监管信息、政策解读、科普信息、药品、医疗器械、化妆品等栏目，基本与中文网站栏目保持一致，今后将努力实现中英文信息同步更新，及时将中国药品、医疗器械、化妆品监管声音传递到世界。(2019-07-19)

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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