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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

Announcement of National Medical Products Administration and National Health Commission on Issuing the *2020 Edition of the Pharmacopoeia of the People's Republic of China*

On July 2, 2020, National Medical Products Administration and National Health Commission issued an announcement on the 2020 Edition of the *Pharmacopoeia of the People's Republic of China*, of which the contents are as follows:

According to the *Drug Administration Law of the People's Republic of China*, the 2020 Edition of the *Pharmacopoeia of the People's Republic of China* reviewed and approved at the plenary meeting of the executive committee of the Eleventh Chinese Pharmacopoeia Commission (ChP) was issued on June 24, 2020, and shall come into force as of December 30, 2020. (July 2, 2020)

国家药品监督管理局 国家卫生健康委发布关于2020年版《中华人民共和国药典》的公告

2020年7月2日，国家药品监督管理局 国家卫生健康委发布关于2020年版《中华人民共和国药典》的公告，内容如下：

根据《中华人民共和国药品管理法》，2020年版《中华人民共和国药典》经第十一届药典委员会执行委员会全体会议审议通过，于2020年6月24日发布，自2020年12月30日起实施。（2020-07-02）

NMPA Issues the Opinions on Reinforcing ADR Monitoring & Evaluation System and Capacity Building

On July 30, 2020, NMPA issued the *Opinions on Reinforcing ADR Monitoring & Evaluation System and Capacity Building*, in order to conscientiously implement the *Drug Administration Law*, *Vaccine Administration Law*, *Regulations for the Supervision and Administration of Medical Devices* and *Regulations for the Supervision and Administration of Cosmetics*, effectively reinforce the system and capacity building for monitoring & evaluation of adverse drug reactions, medical device adverse events, cosmetic adverse reactions, and drug abuse, continuously improve the monitoring & evaluation capacity, and comprehensively promote the safety of drugs, medical devices and cosmetics for public use to protect and promote public health.

(July 30, 2020)

国家药品监督管理局发布进一步加强药品不良反应监测评价体系和能力建设的意见

为认真贯彻落实《药品管理法》《疫苗管理法》《医疗器械监督管理条例》《化妆品监督管理条例》，切实加强药品不良反应、医疗器械不良事件、化妆品不良反应、药物滥用监测评价（以下统称为药品不良反应监测评价）体系和能力建设，不断提高监测评价能力，全面促进公众用药用械用妆安全,保护和促进公众健康，2020年7月30日，国家药监局发布《关于进一步加强药品不良反应监测评价体系和能力建设的意见》。（2020-07-30）

NMPA Issues the Announcement on Three Documents Including the *Working Procedures for Review of Breakthrough Therapy Drugs (Interim)*

In order to cooperate with the implementation of the Provisions for Drug Registration, NMPA has organized to formulate the *Working Procedures for Review of Breakthrough Therapy Drugs (Interim)*, *Working Procedures for Review and Approval of Applications for Conditional Approval of Drug Marketing (Interim)* and *Working Procedures for Priority Review and Approval of Drug Marketing Authorization (Interim)*, which issued on July 7, 2020.

This Announcement shall be implemented as of the date of issuance. The *Opinions on Encouraging Pharmaceutical Innovation via Priority Review & Approval* issued by CFDA in December 2017 shall be abolished simultaneously.

(July 7, 2020)

国家药品监督管理局发布关于《突破性治疗药物审评工作程序（试行）》等三个文件的公告

为配合《药品注册管理办法》实施，国家药品监督管理局组织制定了《突破性治疗药物审评工作程序（试行）》《药品附条件批准上市申请审评审批工作程序（试行）》《药品上市许可优先审评审批工作程序（试行）》，于2020年7月7日发布。

本公告自发布之日起施行。原食品药品监管总局于2017年12月发布的《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）同时废止。（2020-07-07）

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NMPA Issues the *Announcement on Implementing the 2020 Edition of the Pharmacopoeia of the People's Republic of China*

The 2020 Edition of the Pharmacopoeia of the People's Republic of China (hereinafter referred to as 2020 Chinese Pharmacopoeia) has been issued by NMPA and NHC Announcement, and shall come into force as of December 30, 2020. On July 3, NMPA hereby announced the following matters concerning the implementation of the 2020 Chinese Pharmacopoeia:

I. According to the provisions of the Drug Administration Law, drugs shall conform to the national drug standards. Chinese Pharmacopoeia constitutes an important part of the national drug standards, and is a legal technical standard that should be followed by relevant institutions in drug R & D, production (import), distribution, use, supervision and administration.

II. Chinese Pharmacopoeia is primarily composed of General Notices, Monographs and General Technical Requirements. From the date of implementation, all drugs manufactured and marketed shall comply with the relevant technical requirements of the 2020 Chinese Pharmacopoeia.

III. As from the date of implementation, for drug varieties that have been recorded in former editions of pharmacopoeias and the standards promulgated by CFDA or Ministry of Health (MOH), but now are included in the 2020 Chinese Pharmacopoeia, the corresponding former editions of pharmacopoeias and the standards promulgated by CFDA or MOH shall be abolished simultaneously; where those varieties are not recorded in the 2020 Chinese Pharmacopoeia, the corresponding former editions of pharmacopoeias and the standards promulgated by CFDA or MOH shall still prevail, and meanwhile they shall comply with the relevant general technical requirements of the 2020 Chinese Pharmacopoeia; for drug varieties revoked or cancelled after post-marketing evaluation, the corresponding former editions of pharmacopoeias and the standards promulgated by CFDA or MOH shall be abolished.

For preparation specifications and TCM preparation methods that are not recorded in the Monographs of the 2020 Chinese Pharmacopoeia, their quality standards shall comply with the requirements for the same kind varieties specified in the 2020 Chinese Pharmacopoeia, and their specifications and preparation methods shall comply with the original approval documents.

IV. Where the test items recorded in drug registration standards outnumber or differ from those specified in the pharmacopoeia, or the quality indicators are stricter than the pharmacopoeia requirements, the corresponding items and indicators of the registration standard shall be implemented simultaneously while requirements of the pharmacopoeia have to be met.

Where the test items recorded in drug registration standards are fewer than those specified in the pharmacopoeia, or the quality indicators are lower than the pharmacopoeia requirements, the pharmacopoeia provisions shall prevail.

V. Due to the particularity of dissolution, release and other items in quality control, where the registration standards of generic drugs approved in accordance with the quality and efficacy consistency evaluation requirements are different from those specified in the Chinese Pharmacopoeia, NMPA shall elaborate such difference in the review & approval conclusion, the applicant shall submit a proposal to revise the corresponding national drug standard to the Chinese Pharmacopeia Commission within three months upon the approval of corresponding registration application. Before the revision of the Chinese Pharmacopoeia is completed, the approved drug registration standards shall be applied.

VI. To comply with the requirements of the 2020 Chinese Pharmacopoeia, where changes

国家药品监督管理局发布关于实施2020年版《中华人民共和国药典》有关事宜的公告

2020年版《中华人民共和国药典》（以下简称《中国药典》）已由国家药品监督管理局 国家卫生健康委2020年第78号公告发布，自2020年12月30日起实施。7月3日，国家药品监督管理局就实施本版《中国药典》有关事宜公告如下：

一、根据《药品管理法》的规定，药品应当符合国家药品标准。《中国药典》是国家药品标准的重要组成部分，是药品研制、生产（进口）、经营、使用和监督管理等相关单位均应遵循的法定技术标准。

二、《中国药典》主要由凡例、品种正文和通用技术要求构成。自实施之日起，所有生产上市药品应当符合本版《中国药典》相关技术要求。

三、自实施之日起，凡原收载于历版药典、局（部）颁标准的品种，本版《中国药典》收载的，相应历版药典、局（部）颁标准同时废止；本版《中国药典》未收载的，仍执行相应历版药典、局（部）颁标准，但应符合本版《中国药典》的相关通用技术要求，经上市后评价撤销或注销的品种，相应历版药典、局（部）颁标准废止。

本版《中国药典》品种正文未收载的制剂规格、中药的制法，其质量标准按本版《中国药典》同品种相关要求执行，规格项、制法项分别按原批准证明文件执行。

四、药品注册标准中收载检验项目多于或者异于药典规定的，或者质量指标严于药典要求的，应在执行药典要求的基础上，同时执行注册标准的相应项目和指标。

药品注册标准收载检验项目少于药典规定或质量指标低于药典要求的，应执行药典规定。

五、由于溶出度、释放度等项目在质量控制中的特殊性，按照仿制药质量和疗效一致性评价要求核准的仿制药注册标准中有别于《中国药典》的，国家药品监督管理部门在审批结论中予以说明，申请人在相应注册申请获批后三个月之内向国家药典委员会提出修订国家药品标准的建议。在《中国药典》完成修订之前，可按经核准的药品注册标准执行。

六、为符合本版《中国药典》要求，如涉及药品处方、生产工艺和原辅料来源等变更的，药品上市许可持有人、生产企业应按

in drug formulation, production processes, and sources of raw materials and excipients are involved, drug marketing authorization holders and manufacturers shall follow the Provisions for Drug Registration, relevant technical guidance for changes in R & D techniques and the Good Manufacturing Practice for Drugs to conduct in-depth research and verification, obtain approval or complete filing according to relevant change category before implementation or report.

VII. For drugs whose generic names have been revised in the 2020 Chinese Pharmacopoeia, the names specified in the 2020 Chinese Pharmacopoeia shall prevail, and their original names can be transitionally used as former names.

VIII. As from the date of implementation of the 2020 Chinese Pharmacopoeia, the corresponding application dossiers for drug registration application shall comply with the relevant requirements of the 2020 Chinese Pharmacopoeia.

For registration applications that have been accepted with pending technical review before the date of implementation of the 2020 Chinese Pharmacopoeia, the drug regulatory authority shall carry out corresponding review & approval according to the relevant requirements of the 2020 Chinese Pharmacopoeia as from the date of implementation of the 2020 Chinese Pharmacopoeia, and applicants who need to supplement technical information shall complete the supplement at one submission.

Drugs approved for marketing according to the relevant requirements of previous pharmacopoeias after the date of issuance and before the date of implementation of the 2020 Chinese Pharmacopoeia shall comply with the relevant requirements of the 2020 Chinese Pharmacopoeia within 6 months after approval.

IX. Drug marketing authorization holders, manufacturers, and applicants for drug registration shall actively prepare for the implementation of the 2020 Chinese Pharmacopoeia, and in a timely manner report the problems found in practice to the Chinese Pharmacopeia Commission, while continuously study and improve drug quality standards and persistently improve the level of drug quality control.

X. All provincial drug regulatory authorities shall cooperate in the publicity and implementation of the 2020 Chinese Pharmacopoeia, reinforce the supervision and guidance in its implementation, in a timely manner collect and provide feedback on related issues and opinions.

XI. The Chinese Pharmacopeia Commission is responsible for uniformly organizing and coordinating the publicity, implementation, training and technical guidance of the 2020 Chinese Pharmacopoeia, opening up the 2020 Chinese Pharmacopoeia Implementation Column on its official website, and in a timely manner answering questions reflected in implementation.

(July 3, 2020)

照《药品注册管理办法》以及有关变更研究技术指导原则和药品生产质量管理规范等要求进行充分研究和验证，按相应变更类别批准、备案后实施或报告。

七、本版《中国药典》已进行通用名称修订的药品，应使用本版《中国药典》中载明的名称，其原名称可作为曾用名过渡使用。

八、本版《中国药典》实施之日起，提出的药品注册申请，相应申报资料应符合本版《中国药典》相关要求。

本版《中国药典》实施之日前已受理、尚未完成技术审评的注册申请，自本版《中国药典》实施之日起药品监督管理部门应按照本版《中国药典》相关要求开展相应审评审批，申请人需要补充技术资料的应一次性完成提交。

本版《中国药典》发布之日后、实施之日前按原药典标准相关要求批准上市的药品，批准后6个月内应符合本版《中国药典》相关要求。

九、药品上市许可持有人、生产企业和药品注册申请人应积极做好执行本版《中国药典》的准备工作，对在《中国药典》执行过程中发现的问题及时向国家药典委员会报告，同时应持续研究完善药品质量标准，不断提高药品质量控制水平。

十、各省级药品监督管理部门应配合做好2020年版《中国药典》的宣传贯彻，加强本版药典执行中的监督与指导，及时收集和反馈相关问题和意见。

十一、国家药典委员会负责统一组织和协调2020年版《中国药典》的宣贯培训和技术指导工作，在官方网站开辟“2020年版《中国药典》执行专栏”，及时答复执行中反映的问题。 (2020-07-03)

NMPA Issues the Revised Draft of the Blood Products Appendix in the *Good Manufacturing Practice for Drugs (2010 Revision)*

After the implementation of the *Drug Administration Law of the People's Republic of China*, in the light of Article 310 of the *Good Manufacturing Practice for Drugs (2010 Revision)*, NMPA has revised the Blood Products Appendix. The Appendix was issued as a supporting document for the *Good Manufacturing Practice for Drugs (2010 Revision)* on July 2, 2020, and shall come into force as of October 1, 2020.

(July 2, 2020)

国家药品监督管理局发布《药品生产质量管理规范（2010年修订）》血液制品附录修订稿

《中华人民共和国药品管理法》实施后，国家药品监督管理局按照《药品生产质量管理规范（2010年修订）》第三百一十条规定，对《血液制品》附录进行了修订，作为《药品生产质量管理规范（2010年修订）》配套文件于2020年7月2日发布。附录自2020年10月1日起施行。 (2020-07-02)

NMPA Issues the Announcement on the Requirements for the Management of Drug Records and Data (Interim)

To implement the relevant provisions of the *Drug Administration Law* and the *Vaccine Administration Law*, strengthen the management of records and data of drug R & D, production, distribution and use, and ensure that relevant information is true, accurate, complete and traceable, NMPA has organized to formulate the *Requirements for the Management of Drug Records and Data (Interim)*, which was issued on June 24, 2020 and shall come into force as of December 1, 2020.

(June 24, 2020)

国家药品监督管理局发布药品记录与数据管理要求（试行）的公告

为贯彻落实《药品管理法》《疫苗管理法》有关规定，加强药品研制、生产、经营、使用活动的记录和数据管理，确保有关信息真实、准确、完整和可追溯，国家药品监督管理局组织制定了《药品记录与数据管理要求（试行）》，于2020年6月24日发布，自2020年12月1日起施行。 （2020-06-24）

Medical devices

NMPA Issues the Notice on Matters Related to Further Strengthening Management for Mandatory Industry Standards of Medical Devices

To further unify the understanding of mandatory industry standards, and truly promote the implementation of mandatory industry standards of medical devices, in accordance with the *Standardization Law of the People's Republic of China*, the *Regulations for the Supervision and Administration of Medical Devices*, the *Provisions for Mandatory National Standards* and *the Provisions for Medical Device Standards*, on July 7, 2020, NMPA issued the notice on matters related to further strengthening management for mandatory industry standards of medical devices, requiring drug regulatory authorities at all levels to effectively maintain the legal status of mandatory industry standards, further improve the mandatory industry standard system, promote the drafting and implementation of mandatory industry standards, reinforce the publicity, implementation and training, standardize the implementation of mandatory industry standards, and reinforce the evaluation on implementation of mandatory industry standards. (July 9, 2020)

医疗器械

国家药品监督管理局发布关于进一步加强医疗器械强制性行业标准管理有关事项的通知

为进一步统一对强制性行业标准的认识，切实推进医疗器械强制性行业标准规范有效实施，根据《中华人民共和国标准化法》《医疗器械监督管理条例》《强制性国家标准管理办法》和《医疗器械标准管理办法》，2020年7月7日，国家药品监督管理局就进一步加强医疗器械强制性行业标准管理有关事项发布通知，要求各级药品监管部门切实维护强制性行业标准的法律地位、进一步完善强制性行业标准体系、完善强制性行业标准起草和实施、加强强制性行业标准的宣贯培训、规范强制性行业标准的执行、强化强制性行业标准的实施评估。 （2020-07-09）

NMPA Issues the Announcement on 6 Technical Review Guidances for Registration Including the Technical Review Guidance for the Registration of Disposable Breast localization Wire

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, NMPA has organized to formulate the *Technical Review Guidance for the Registration of Disposable Breast localization Wire, Technical Review Guidance for the Registration of Dural (Spinal) Patches, Technical Review Guidance for the Registration of Customized and Personalized Equivalent Models of Bone Implants, Technical Review Guidance for the Registration of Finite Element Analysis Data of Orthopedic Metal Implants, Guidance for Clinical Trials of Hernia Repair Meshes,* and *Guidance for Animal Study of Bioabsorbable Coronary Artery Drug-Eluting Stents*, and they were issued on July 7, 2020. (July 9, 2020)

国家药品监督管理局发布关于一次性使用乳腺定位丝注册技术审查等6项注册技术审查指导原则的通告

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《一次性使用乳腺定位丝注册技术审查指导原则》《硬脑（脊）膜补片注册技术审查指导原则》《定制式个性化骨植入物等效性模型注册技术审查指导原则》《骨科金属植入物有限元分析资料注册技术审查指导原则》《疝修补补片临床试验指导原则》《生物可吸收冠状动脉药物洗脱支架动物实验研究指导原则》，于2020年7月7日发布。 （2020-07-09）

NMPA Issues the Writing Specification for Periodic Risk Evaluation Reports of Medical Devices

To implement the requirements of the *Provisions for Medical Device Adverse Event Monitoring and Re-evaluation* (SAMR and NHC Order No.1), regulate and guide medical device registration applicants to write the periodic risk evaluation reports, NMPA has organized to formulate the *Writing Specification for Periodic Risk Evaluation Reports of Medical Devices*, which was issued on June 24, 2020. (June 24, 2020)

国家药品监督管理局发布医疗器械定期风险评价报告撰写规范

为落实《医疗器械不良事件监测和再评价管理办法》（国家市场监督管理总局 国家卫生健康委员会令 第1号）有关要求，规范并指导医疗器械注册人撰写定期风险评价报告，国家药品监督管理局组织制定了《医疗器械定期风险评价报告撰写规范》，于2020年6月30日发布。（2020-07-02）

Annual Report

2019 Drug Review Annual Report Is Released

On July 30, 2020, the Center for Drug Evaluation released the 2019 Drug Review Annual Report, some contents of which are summarized as follows:

As a milestone in the history of China's legal system development in drug administration, the year of 2019 saw the newly formulated *Vaccine Administration Law*, marking the first comprehensive law for vaccine administration in the world, and the newly revised *Drug Administration Law*, marking an across-the-board revision in the past 20 years, all of which symbolizes, in the form of the law, the crystallization of the deployment of the Party Central Committee and the State Council, the expectations of the people and the experience of review system reform, providing a powerful legal safeguard to consolidate and promote the reform of the drug review and approval system. In 2019, the Center for Drug Evaluation (hereinafter referred to as CDE), under the strong leadership of National Medical Products Administration (hereinafter referred to as NMPA), carefully studied and implemented the *Drug Administration Law* and the *Vaccine Administration Law*, continued to promote the reform of the drug review and approval system, actively promote scientific management system through process streamlining for drug review, adhered to law-based, open & transparent, service-centered and scientifically standardized review, to effectively guarantee the safety, effectiveness and accessibility of drugs, and protect the people's health rights and interests.

- **Acceptance of drug registration applications**

In 2019, CDE accepted a total of 8082 new registration applications (including 5 drug-device combination products, counted by acceptance numbers, the same below), of which 6199 applications are subject to technical review (including 4907 applications subject to technical review and administrative approval of CDE), and the rest of 1878 applications are subject to direct administrative approval (not requiring technical review, the same below).

Overview

Of the 8077 drug registration applications accepted by CDE, 80.2% (6475) of the total are chemical drugs applications in 2019. See Figure 1 for the acceptance of registration applications for various classes of drugs in 2016-2019.

In 2019, 6199 registration applications requiring technical review were accepted, increased by 11.21% as compared with those in 2018. Among them, 4937 registration applications were for chemical drugs, increased by 10.72% as compared with those in 2018, accounting for 79.64% of

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《2019年度药品审评报告》发布

2020年7月30日，药品审评中心发布《2019年度药品审评报告》，部分内容如下：

2019年是药品监管法律建设史上具有里程碑意义的一年，新制定的《疫苗管理法》是世界首部综合性疫苗管理法律，新修订的《药品管理法》是近20年来的一次全面修订，《疫苗管理法》《药品管理法》将党中央、国务院的部署，人民群众的期盼，审评制度改革的经验，以法律的形式固定下来，为巩固和推进药品审评审批制度改革提供了有力的法律保障。这一年，国家药品监督管理局药品审评中心（以下简称药审中心）在国家药品监督管理局（以下简称国家局）的坚强领导下，认真学习贯彻《药品管理法》《疫苗管理法》，持续推动药品审评审批制度改革，积极构建药品审评以流程为导向的科学管理体系，坚持依法依规、公开透明、服务为本、科学规范审评，切实保障药品安全有效可及，维护人民群众健康权益。

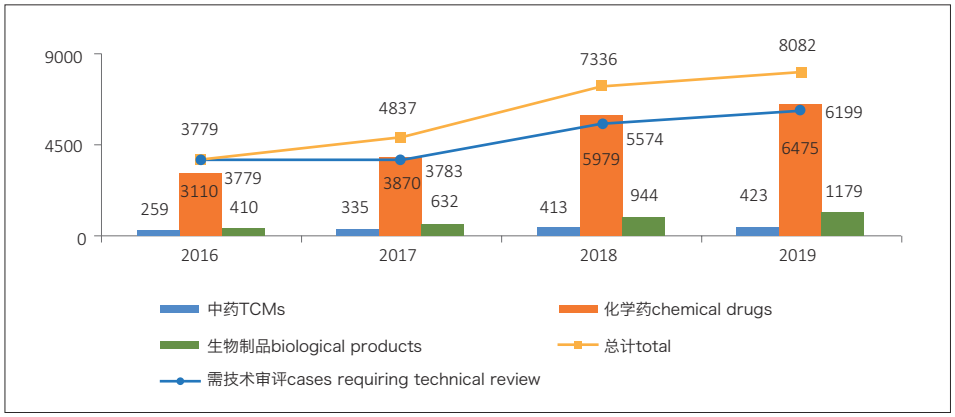
• 药品注册申请受理情况

2019年，药审中心受理新注册申请8082件（含器械组合产品5件，以受理号计，下同），其中需技术审评的注册申请6199件（含4907件需药审中心技术审评和行政审批的注册申请），直接行政审批（无需技术审评，下同）的注册申请1878件。

总体情况

药审中心受理的8077件药品注册申请中，化学药注册申请受理量为6475件，占2019年全部注册申请受理量的80.2%，2016—

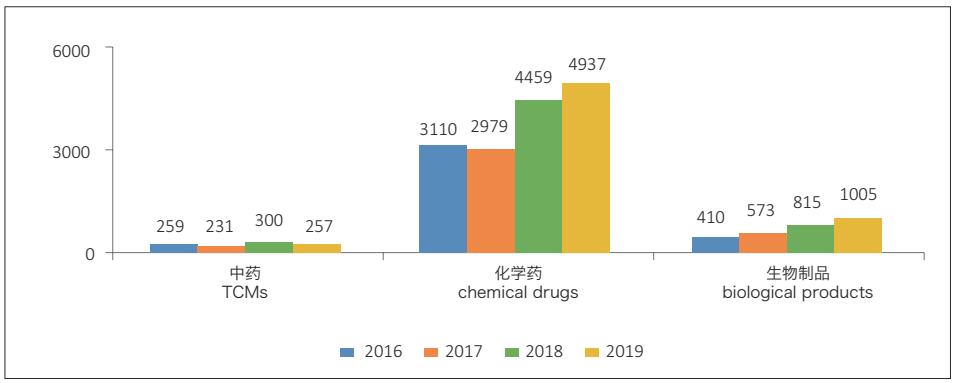
图1 2016-2019年各类药品注册申请受理情况
Figure 1 Acceptance of registration applications of various classes of drugs in 2016-2019



注：
1. 2019年受理量中含5件器械组合产品的注册申请，故上图中2019年受理注册申请总量大于中药、化学药、生物制品受理注册申请之和；
2. 药审中心的直接行政审批工作自2017年开始，所以2016年无直接行政审批注册申请，所有受理注册申请均需技术审评。

Notes:
1. The number of applications accepted in 2019 contains the registration of 5 drug-device combination products, and therefore the total number of applications accepted for registration in 2019 in the above figure exceeds the sum of applications for registration of TCMs, chemical drugs and biological products;
2. The direct administrative approval of CDE started in 2017, and therefore there is no direct administrative approval of registration applications in 2016, for all accepted registration applications are subject to technical review.

图2 2017—2019年需技术审评的各类药品注册申请受理情况
Figure 2 Acceptance of registration applications of various classes of drugs requiring technical review in 2017-2019



the total number of registration applications requiring technical review; 257 registration applications were for TCMs, decreased by 14.33% as compared with those in 2018; 1005 registration applications were for biological products, increased by 23.3% as compared with those in 2018. The details of acceptance of registration applications for chemical drugs, TCMs and biological products requiring technical review in 2016-2019 are shown in Figure 2.

CDE has accepted a total of 700 applications (involving 319 varieties, increased by 20.8% as compared with those in 2018) for the registration of Class 1 innovative drugs (the number of varieties of chemical drugs is based on the statistical analysis of active ingredients, while the varieties of TCMs and biological products are all counted by their generic names, the same below), covering 302 INDs (increased by 26.4% as compared with those in 2018) and 17 NDAs (decreased by 8 varieties as compared with those in 2018) for Class 1 innovative drugs.

- **Review and approval for drug registration applications**

1. Completion of review and approval annually

From 2015 to 2018, CDE basically solved the backlog of drug registration applications by reinforcing review power and improving the efficiency of review from all aspects such as expanded review channels, enhanced

2019年各类药品注册申请受理情况详见图1。

2019年，受理需技术审评的注册申请6199件，较2018年增加11.21%，其中化学药注册申请为4937件，较2018年增长了10.72%，占全部需技术审评的注册申请受理量的79.64%；中药注册申请257件，较2018年降低了14.33%；生物制品注册申请1005件，较2018年增长了23.3%。2016-2019年需技术审评的化学药、中药和生物制品注册申请受理情况详见图2。

药审中心受理1类创新药注册申请共700件（319个品种），（化学药的品种数以活性成分统计，中药和生物制品的品种数均以药品通用名称统计，下同），品种数较2018年增长了20.8%。其中，受理1类创新药的新药临床试验（IND）申请302个品种，较2018年增长了26.4%；受理1类创新药的新药上市申请（NDA）17个品种，较2018年减少了8个品种。

- **药品注册申请审评审批情况**

1. 全年审评审批完成情况

2015年至2018年期间药审中心通过扩充审评通道、强化审评项目管理、大规模招聘人员、借调省局人员等措施多渠道扩增审评力量、提高审评效率，使得药品注册申请积压基本得以解决，药审中心的工作重点已经由解决药品注册申请积压逐渐过渡为提升药品注册申请的按时限审评审批率，2019年药审中心实现了中药、化学药、生物制品各类注册申请按时限审评审批率超过90%，基本完成了国务院《关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号，以下简称44号文件）确定2018年实现按规定时限审批的工作目标。

2019年完成审评审批的注册申请共8730件（含器械组合产品5件），其中完成需技术审评的注册申请6817件（含4075件需药审中心技术审评和行政审批注册申请），完成直接行政审批的注册申请1908件。2019年底在审评审批和等待审评审批的注册申请已由2015年9月高峰时的近22000件降至4423件（不含完成审评因申报资料缺陷等待申请人回复补充资料的注册申请），巩固了44号文件要求解决注册申请积压的改革成效。

2019年4423件在审评审批和等待审评审批的注册申请中，启动审评3334件，审评结束等待核查450件，处于暂停审评计时等待关联品种（290件）、等待申请人核对质标说明书包装标签工艺（235件）、等待检验报告（36件）等情况中的任务共639件。

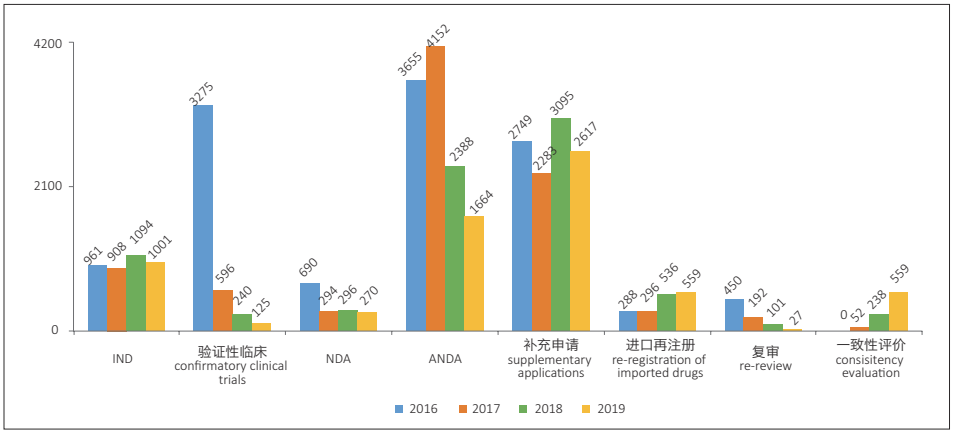
review project management, large-scale recruitment, seconded personnel from provincial bureaus, and other measures. The work focus of CDE gradually shifted from reducing the backlog of registration applications to improving the rate of on-time review and approval of drug registration applications. In 2019, CDE accomplished over 90% of on-time review & approval of registration applications for TCMs, chemical drugs and biological products, thus basically completed the work objective set forth in the *Opinions of the State Council on Reforming the Review & Approval System for Drugs and Medical Devices* (State Council [2015] No.44, hereinafter referred to as Document No.44).

In 2019, a total of 8730 registration applications (including 5 drug-device combination products) were subject to review and approval, of which 6817 applications were subject to technical review (including 4075 applications subject to technical review and administrative approval of CDE), and the rest 1908 applications were subject to direct administrative approval. The number of registration applications subject to review and approval and those pending for review and approval has dropped from nearly 22,000 at the peak of September 2015 to 4423 (excluding those applications whose review have been completed and are pending for the Applicants' supplementary materials) by the end of 2019, consolidating the reform accomplishment of liquidating the backlog of registration applications as required by Document No.44.

In 2019, among the 4423 registration applications subject to review and approval and those pending for review and approval, 3334 applications were initiated for review, 450 applications were pending for verification at the end of the review; and the remaining 639 review tasks covered 290 applications subject to suspended review with time-keeping while waiting for related varieties, and 235 applications waiting for the applicant to verify the quality standards, package inserts and labels, and 36 applications waiting for test reports.

Among the 6817 registration applications with completed technical review, 300 applications were for TCMs, 1104 applications were for biological products, and 5413 applications were for chemical drugs (accounting for about 79% of all completed reviews).

图 2016—2019年各类注册申请审评完成情况
Figure Completion of reviews for various types of registration applications in 2016-2019



注：2019年含5件器械组合产品的注册申请，故上图中2019年注册申请总量大于中药、化学药、生物制品注册申请之和。

Notes: The number of applications accepted in 2019 contains the registration of 5 drug-device combination products, and therefore the total number of applications accepted for registration in 2019 in the above figure exceeds the sum of applications for registration of TCMs, chemical drugs and biological products.

2. Completion of reviews for various types of registration applications

CDE completed the reviews for 1001 IND applications (including 1 drug-device combination product), 270 NDA reviews (including 1 drug-device combination product), and 1664 ANDA reviews (including 3 drug-device combination products).

3. Approved reviews

In 2019, CDE reviewed and approved 926 IND applications, 164 NDAs, 654 ANDAs, and 260 applications for consistency evaluation of oral solid preparations (95 varieties based on the statistical analysis of active ingredients, and 107 varieties counted by their generic names), and the number of varieties was increased by 66.7% compared with that in 2018 (57 varieties).

CDE reviewed and approved the marketing of 10 varieties of Class 1 innovative drugs, and 58 varieties of imported brand-name drugs (including new indications).

(July 30, 2020)

完成技术审评的6817件注册申请中，中药注册申请300件，生物制品注册申请1104件，化学药注册申请为5413件，化学药注册申请约占全部审评完成量的79%。

2. 各类注册申请审评完成情况

药审中心完成IND申请审评1001件（含1件器械组合产品），完成NDA审评270件（含1件器械组合产品），完成ANDA审评1664件（含3件药械组合产品）。

3. 审评通过情况

2019年，药审中心审评通过批准IND申请926件，审评通过NDA 164件，审评通过ANDA 654件，审评通过批准口服固体制剂一致性评价申请260件（按活性成分统计95个品种，按通用名统计107个品种），品种数较2018年（57个品种）同比增长66.7%。

审评通过上市1类创新药10个品种，审评通过进口原研药58个品种（含新适应症）。

(2020-07-30)

Notes:
- All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
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