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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

NMPA Party Committee Studied and Implemented Important Instructions Made by General Secretary Xi Jinping in the Inspection of COVID-19 Epidemic in Hubei

In the afternoon of March 11, NMPA held an enlarged Party Committee Meeting and a Steering Committee Meeting for Epidemic Response to study and implement the important instructions made by General Secretary Xi Jinping in the inspection of the novel coronavirus epidemic (COVID-19) in Hubei.

The Meeting pointed out that during the critical period of the fight against the COVID-19 epidemic, General Secretary Xi's advent in Wuhan, Hubei to inspect the epidemic prevention & control, visit and sympathize with frontline staff and residents, together with his cheer-ups, has fully manifested the CPC's tenet and sentiment of putting the people's lives and health in the first place, and the firm determination to win the People's comprehensive against epidemic and defense for prevention & control.

The Meeting has made decisions to to: 1. speed up the construction of the National COVID-19 Medical Device Emergency Response Platform, improve the coordination mechanism, and form a joint effort; 2. continue to engage in efficient emergency approval, actively connect with relevant R&D enterprises and scientific research teams, reinforce services for the support of scientific research for key technological breakthroughs, and promote expedited marketing of safe and reliable vaccines, drugs, and medical devices with clinically significant outcomes; 3. continue to strengthen quality supervision, strengthen the supervision of marketed products in the wake of emergency approval, strengthen the supervision and inspection of drugs incorporated into the COVID-19 diagnosis and treatment protocol, strengthen the management of approved clinical trials of drugs, severely crack down on violations of laws and regulations, and ensure the quality and safety of drugs and medical devices used for epidemic prevention & control; 4. sort out and summarize the experiences and deficiencies, and promote the construction of drug administration system and supervision capacity in combination with the development, formulation and revision of corresponding laws and regulations and the development of the *Fourteenth Five-Year Plan for Drug Administration*; and 5. coordinate the work arrangement for drug administration in 2020, ensure effective and orderly implementation, actively support the resumption of work and production in pharmaceutical companies, seek progress while maintaining stability of drug safety, and promote high-quality development of pharmaceutical industry, to make due contributions to the successful construction of a moderately well-off society in an all-round way, and victory in poverty alleviation objectives.

(March 11, 2020)

国家药品监督管理局党组学习贯彻习近平总书记在湖北考察新冠肺炎疫情防控重要讲话精神

3月11日下午，国家药品监督管理局召开党组扩大会议暨疫情应对工作领导小组会议，学习贯彻习近平总书记在湖北考察新冠肺炎疫情防控工作时的重要讲话精神。

会议指出，在抗击新冠肺炎疫情关键时期，习近平总书记亲赴湖北武汉考察疫情防控工作，看望慰问一线工作人员和居民群众，为大家加油鼓劲，充分彰显了以习近平同志为核心的党中央始终把人民群众生命安全和身体健康放在第一位的宗旨情怀和打赢疫情防控人民战争、总体战、阻击战的坚定决心。

会议要求，一要加快国家新冠肺炎药品医疗器械应急平台建设，完善协调机制，形成工作合力。二要继续做好应急审批工作，主动对接相关研发企业和科研团队，强化科研攻关服务支持，推动安全可靠、临床效果显著的疫苗、药品和医疗器械加快上市。三要持续加强质量监管，加强应急审批上市产品监管，强化对纳入新冠肺炎诊疗方案药品的监督检查，加强对已批准药物临床试验管理，严厉打击违法违规行为，保障疫情防控用药械质量安全。四要梳理总结经验不足，结合法规制度制修订和“十四五”规划编制，推进药品监管体系和监管能力建设。五要统筹全年工作安排，有序抓好任务落实，积极支持医药企业复工复产，确保药品安全形势稳中向好，促进医药产业高质量发展，为实现决胜全面建成小康社会、决胜脱贫攻坚目标作出应有贡献。 （2020-03-11）

NMPA Emergency Approval of SARS-CoV-2 Detection Products

Recently, NMPA has successively conducted emergency approval of two SARS-CoV-2 IgM/IgG antibody detection kits (GICA) from Nanjing Vazyme Biotech Co., Ltd. and Zhuhai Livzon Diagnostics Inc.. Marketing approval for the above reagents, which use immunochromatographic technology via indirect approach for qualitative detection of IgM and IgG antibodies, can further expand the supply of rapid detection reagents and

国家药品监督管理局应急审批新型冠状病毒检测产品

近日，国家药品监督管理局先后应急审批通过南京诺唯赞医疗科技有限公司和珠海丽珠试剂有限公司2个新型冠状病毒（2019-nCoV）IgM/IgG抗体检测试剂盒（胶体金法）。上述抗体检测试剂采用免疫层析技术，通过间接法定性

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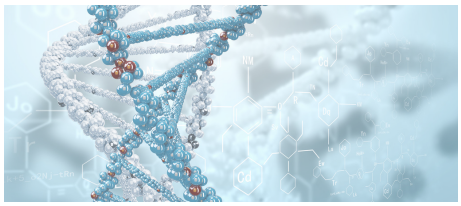
serve the needs of epidemic prevention & control.

To date, NMPA has approved a total of 11 SARS-CoV-2 nucleic acid detection reagents and 8 antibody detection reagents.

(March 16, 2020)



检测人新型冠状病毒（2019-nCoV）IgM和IgG抗体。上述产品获批上市，进一步扩大了快速检测试剂的供应，服务疫情防控需要。

截至目前，国家药品监督管理局共批准新冠病毒核酸检测试剂11个，抗体检测试剂8个。（2020-03-16）

Announcement of NMPA on Revising the Package Inserts of Nicotinic Acid Injections

To further protect drug safety for the people, on March 17, 2020, NMPA issued an Announcement with decisions made to revise the Entries of [contraindications], [adverse reactions] and [precautions] on the package inserts of nicotinic acid injections (including nicotinic acid injection and nicotinic acid for injection).

(March 17, 2020)

国家药品监督管理局发布关于修订烟酸注射剂说明书的公告

为进一步保障公众用药安全，2020年3月17日，国家药品监督管理局发布公告，决定对烟酸注射剂（包括烟酸注射液、注射用烟酸）说明书【不良反应】、【禁忌】、【注意事项】项进行修订。（2020-03-17）

Announcement of NMPA on Revising the Package Inserts of hydrocortisone injection and hydrocortisone sodium succinate for injection

To further protect drug safety for the people, on March 17, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of hydrocortisone injection and hydrocortisone sodium succinate for injection.

(March 17, 2020)

国家药品监督管理局发布关于修订氢化可的松注射液、注射用氢化可的松琥珀酸钠说明书的公告

为进一步保障公众用药安全，2020年3月17日，国家药品监督管理局发布公告，决定对氢化可的松注射液、注射用氢化可的松琥珀酸钠说明书【不良反应】、【注意事项】等项进行修订。（2020-03-17）

Announcement of NMPA on Revising the Package Inserts of Probucol

To further protect drug safety for the people, on March 17, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of probucol. (March 11, 2020)

国家药品监督管理局发布关于修订普罗布考说明书的公告

为进一步保障公众用药安全，2020年3月11日，国家药品监督管理局发布关于修订普罗布考说明书的公告，决定对普罗布考说明书【不良反应】、【注意事项】等项进行修订。（2020-03-11）

NMPA Released Five Informatization Standards Including the Basic Data Set for Traceability of Drug Marketing Authorization Holders and Manufacturers

To implement the provisions of the *Drug Administration Law of the People's Republic of China*, in accordance with the requirements of the *Guiding Opinions of the China National Drug Administration on the Construction of*

国家药品监督管理局发布《药品上市许可持有人和生产企业追溯基本数据集》等5项信息化标准

为贯彻落实《中华人民共和国药品管理法》规定，按照《国家药品监督管理局关于药品信息化追溯体系建设的指导意见》（国

Drug Information Traceability System (CNDA Department of Drug Supervision [2018] No. 35) and other documents, NMPA organized the formulation of the *Basic Data Sets for Traceability of Drug Marketing Authorization Holders and Manufacturers, Basic Data Sets for Traceability of Drug Distributors, Basic Data Sets for Traceability of Drug Using Units, Basic Data Sets for Traceable Drugs for Consumers, and Basic Technical Requirements for Traceability Data Exchange of Drugs*, which were issued on March 11, 2020, and effective as of the issuing date.

(March 11, 2020)

药监药管〔2018〕35号）等文件要求，国家药品监督管理局组织制订了《药品上市许可持有人和生产企业追溯基本数据集》《药品经营企业追溯基本数据集》《药品使用单位追溯基本数据集》《药品追溯消费者查询基本数据集》《药品追溯数据交换基本技术要求》等5项信息化标准，于2020年3月11日发布，自发布之日起实施。（2020-03-11）

Announcement of NMPA on Revising the Package Inserts of triamcinolone injection

To further protect drug safety for the people, on March 6, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of triamcinolone acetonide injections (including Triamcinolone Acetonide Acetate Injection, Triamcinolone Acetonide Injection).

(March 6, 2020)

国家药品监督管理局发布关于修订曲安奈德注射剂说明书的公告

为进一步保障公众用药安全，2020年3月6日，国家药品监督管理局发布公告，决定对曲安奈德注射剂（包括醋酸曲安奈德注射液、曲安奈德注射液）说明书【不良反应】、【注意事项】等项进行修订。（2020-03-06）

Announcement of NMPA on Revising the Package Inserts of Diclofenac Sodium Suppositories

To further protect drug safety for the people, on March 17, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of Diclofenac Sodium Suppositories.

(March 6, 2020)

国家药品监督管理局发布关于修订双氯芬酸钠栓说明书的公告

为进一步保障公众用药安全，2020年3月6日，国家药品监督管理局发布公告，决定对双氯芬酸钠栓说明书【不良反应】、【注意事项】等项进行修订。（2020-03-06）

Announcement of NMPA on Applying 11 ICH Guidelines Including Q2 (R1): Validation of Analytical Procedures: Text and Methodology

On January 21, 2020, NMPA issued the *Announcement of NMPA on Applying 11 ICH Guidelines Including Q2 (R1): Validation of Analytical Procedures: Text and Methodology,* which reads as follows:

To keep pace with the international technical standards for drug registration, NMPA has decided to apply 11 ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines, including the *Q2(R1): Validation of Analytical Procedures: Text and Methodology*. The relevant matters are hereby announced as

国家药品监督管理局发布关于适用《Q2（R1）：分析方法论证：正文和方法学》等11个国际人用药品注册技术协调会指导原则的公告

2020年1月21日，国家药品监督管理局发布关于适用《Q2（R1）：分析方法论证：正文和方法学》等11个国际人用药品注册技术协调会指导原则的公告，内容如下：

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《Q2（R1）：分析方法论证：正文和方法学》等11个国际人用药品注册技术协调会（ICH）指导原则（详见附件）。现就有关事项公告如下。

一、申请人需在现行药学研究技术要求基础上，尽早按照ICH指导原则的要求开

follows.

1. Applicants must conduct research in accordance with the ICH guidelines ASAP based on the current technical requirements for pharmaceutical research; pharmaceutical research that begins 6 months after the issuance date of this Announcement (based on the time point of the trial record) shall apply the ICH guidelines.
2. Relevant technical guidelines can be found on the website of NMPA Center for Drug Evaluation, who is responsible for related technical guidance in the implementation of this Announcement.

(January 22, 2020)

展研究；本公告发布之日起6个月后开始的药学研究（以试验记录时间点为准），适用ICH指导原则。

二、相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。 (2020-01-22)

Announcement of NMPA on Recommended Application of 4 ICH Guidelines Including Q8 (R2): Pharmaceutical Development

On January 21, 2020, NMPA issued a notice on recommending the application of ICH Guideline *Q8 (R2): Pharmaceutical Development*, which reads as follows:

To keep pace with the international technical standards for drug registration, NMPA has decided to recommend the application of 4 ICH Guidelines, including the *Q8(R2): Pharmaceutical Development.* The relevant matters are hereby announced as follows.

1. From the date of issuance of this Announcement, applicants are recommended to follow ICH's *Q8 (R2): Pharmaceutical Development, Q9: Quality Risk Management, Q10: Pharmaceutical Quality System, Q11: Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)* and Q & A documents.
2. Relevant technical guidelines can be found on the website of NMPA Center for Drug Evaluation, who, together with Center for Food and Drug Inspection, is responsible for related technical guidance in the implementation of this Announcement.

(January 22, 2020)

国家药品监督管理局发布关于推荐适用《Q8（R2）：药品研发》等4个国际人用药品注册技术协调会指导原则的公告

2020年1月21日，国家药品监督管理局 发布关于推荐适用《Q8（R2）：药品研发》 国际人用药品注册技术协调会指导原则的公 告，内容如下：

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定推荐适用《Q8（R2）：药品研发》等4个国际人用药品注册技术协调会（ICH）指导原则。现就有关事项公告如下。

一、本公告发布之日起，推荐申请人 按照ICH《Q8（R2）：药品研发》、《Q9：质 量风险管理》、《Q10：药品质量体系》、 《Q11：原料药开发和生产（化学实体和生物 技术/生物实体药物）》及问答文件的要求开 展相关研究。

二、相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心、药品核查中心负责做好本公告实施过程中的相关技术指导工作。 (2020-01-22)

Announcement of NMPA on Revising the Package Inserts of Drugs Containing Pipemidic Acid

To further protect drug safety for the people, on January 21, 2020, NMPA issued an announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of drugs containing pipemidic acid (including pipemidic acid tablets, capsules, and granules).

(January 21, 2020)

国家药品监督管理局发布关于修订含吡哌酸药品说明书的公告

为进一步保障公众用药安全，2020年1月21日，国家药品监督管理局发布公告，决定对含吡哌酸药品（包括吡哌酸片、吡哌酸胶囊和吡哌酸颗粒）说明书【不良反应】、【禁忌】等项进行修订。 (2020-01-21)

Announcement of NMPA, GAC, and SAMR on Implementing the Measures for the Administration of Imported Medicinal Materials

On January 16, 2020, the National Medical Products Administration, the General Administration of Customs and the State Administration for Market Regulation issued the *Announcement on Implementing the Measures for the Administration of Imported Medicinal Materials* and related matters to clarify issues pertaining to the application and approval of initial import, record filing and port inspection of imported medicinal materials.

(January 16, 2020)

国家药品监督管理局 海关总署 市场监管总局发布《关于实施<进口药材管理办法>有关事项的公告》

2020年1月16日，国家药品监督管理局 海关总署 市场监管总局发布《关于实施<进口药材管理办法>有关事项的公告》，就首次进口药材的申请与审批、进口药材的备案、进口药材的口岸检验相关内容进行了明确。（2020-01-16）

Medical Devices

NMPA Issued the *Guidelines for the Verification of Medical Device Registration Quality Management System*

To strengthen the supervision and guidance over medical device product registration and further improve the quality of medical device registration QMS verification, NMPA has organized the formulation of and released on March 17, 2020 the *Guidelines for Medical Device Registration Quality Management System Verification.*

(March 17, 2020)

医疗器械

国家药品监督管理局发布《医疗器械注册质量管理体系核查指南》

为加强医疗器械产品注册工作的监督和指导，进一步提高医疗器械注册质量管理体系核查工作质量，国家药品监督管理局组织制定了《医疗器械注册质量管理体系核查指南》，于2020年3月17日发布。（2020-03-17）

NMPA Issued the *Administrative Measures for Sampling Inspection of Medical Device Quality*

To strengthen medical device administration and standardize the sampling inspection of medical device quality, NMPA has organized the revision of and released on March 13, 2020 the *Administrative Measures for Sampling Inspection of Medical Device Quality. The Administrative Regulations on Quality Supervision and Sampling Inspection of Medical Devices* (CFDA Department of Medical Device Supervision [2013] No. 212) and the *Work Procedures for National Medical Device Sampling Inspection* (CFDA General Office [2014] No. 213) issued by the former China Food and Drug Administration shall be repealed simultaneously.

(March 13, 2020)

国家药品监督管理局印发《医疗器械质量抽查检验管理办法》

为加强医疗器械监督管理，规范医疗器械质量抽查检验工作，国家药监局组织修订了《医疗器械质量抽查检验管理办法》，于2020年3月13日发布。原国家食品药品监督管理总局发布的《医疗器械质量监督抽查检验管理规定》（食药监械监〔2013〕212号）和《国家医疗器械抽查检验工作程序》（食药监办〔2014〕213号）同时废止。（2020-03-13）

NMPA Issued 4 Guidelines for Technical Review of the Registration of EB Virus Nucleic Acid Detection Reagents

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on March 10, 2020 the *Guidelines for Technical Review of the Registration of EB Virus Nucleic Acid Detection Reagents, Guidelines for Technical Review of the Registration of HBV e*

国家药品监督管理局发布EB病毒核酸检测试剂等4项注册技术审查指导原则

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《EB病毒核酸检测试剂注册技术审查指导原则》《乙型肝炎病毒e抗原、e抗体检测试剂注册技术审查指导原

Antigen, e Antibody Detection Reagents, Guidelines for Technical Review of the Registration of Thalassemia-Related Gene Detection Reagents, and Guidelines for Technical Review of the Registration of HBV-Resistant Gene Mutation Detection Reagents. (March 10, 2020)

则》《地中海贫血相关基因检测试剂注册技术审查指导原则》《乙型肝炎病毒耐药相关的基因突变检测试剂注册技术审查指导原则》，于2020年3月10日发布。（2020-03-10）

NMPA Issued the Fundamental Principles for Medical Device Safety and Performance

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on March 10, 2020 the *Fundamental Principles for Medical Device Safety and Performance.*

(March 10, 2020)

国家药品监督管理局发布医疗器械安全和性能基本原则

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医疗器械安全和性能的基本原则，于2020年3月10日发布。（2020-03-10）

NMPA Issued the *Guidelines for Technical Review of the Registration of Semiconductor Laser Hair Removal Machines*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on March 10, 2020 the *Guidelines for Technical Review of the Registration of Semiconductor Laser Hair Removal Machines.*

(March 10, 2020)

国家药品监督管理局发布半导体激光脱毛机注册技术审查指导原则

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半导体激光脱毛机注册技术审查指导原则，于2020年3月10日发布。（2020-03-10）

SFDA Issued the *Guidelines for Technical Review of the Registration of Implantable Left Ventricular Assist System*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on March 10, 2020 the *Guidelines for Technical Review of the Registration of Implantable Left Ventricular Assist System.*

(March 10, 2020)

国家药品监督管理局发布植入式左心室辅助系统注册技术审查指导原则

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植入式左心室辅助系统注册技术审查指导原则，于2020年3月10日发布。（2020-03-10）

NMPA Issued 2 Guidelines for Technical Review of the Registration of X-ray Image Guided Systems for Radiotherapy and Positron Emission / X-Ray Computed Tomography Systems

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the

国家药品监督管理局发布用于放射治疗的X射线图像引导系统和正电子发射/X射线计算机断层成像系统2项注册技术审查指导原则

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《用于放射治疗的X

formulation of and released on March 10, 2020 the *Guidelines for Technical Review of the Registration of X-ray Image Guided Systems for Radiotherapy* and *Guidelines for Technical Review of the Registration of Positron Emission / X-Ray Computed Tomography Systems*.

(March 10, 2020)

射线图像引导系统注册技术审查指导原则》和《正电子发射/X射线计算机断层成像系统注册技术审查指导原则》，于2020年3月10日发布。（2020-03-10）

NMPA Issued 7 Guidelines for Technical Review of the Registration of Colloidal Gold Immunochromatographic Analyzer

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on March 5, 2020 the *Guidelines for Technical Review of the Registration of Colloidal Gold Immunochromatographic Analyzers, Guidelines for Technical Review of the Registration of Follicle-stimulating Hormone Detection Reagents, Guidelines for Technical Review of the Registration of Creatinine Detection Reagents, Guidelines for Technical Review of the Registration of Antinuclear Antibody Detection Reagents, Guidelines for Technical Review of the Registration of Antithyroid Peroxidase Antibody Assay Reagents, Guidelines for Technical Review of the Registration of Glycated Albumin Assay Reagents,* and the *Guidelines for Technical Review of the Registration of Total Bile Acid Assay Reagents.*

(March 5, 2020)

国家药品监督管理局发布胶体金免疫层析分析仪等7项注册技术审查指导原则

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《胶体金免疫层析分析仪注册技术审查指导原则》《促卵泡生成素检测试剂注册技术审查指导原则》《肌酐检测试剂注册技术审查指导原则》《抗核抗体检测试剂注册技术审查指导原则》《抗甲状腺过氧化物酶抗体测定试剂注册技术审查指导原则》《糖化白蛋白测定试剂注册技术审查指导原则》和《总胆汁酸测定试剂注册技术审查指导原则》，于2020年3月5日发布。（2020-03-05）

NMPA Issued the Announcement on 6 Industry Standards Including Protective devices against diagnostic medical X-radiation – Part 1: Determine of attenuation properties of materials

On March 5, 2020, NMPA issued the *Announcement on 6 Industry Standards Including Medical Diagnostic X-Ray Radiation Protective Devices-Part 1: Determination of Material Attenuation Performance,* which reads as follows:

Six medical device industry standards including YY / T 0292.1-2020 *Medical Diagnostic X-ray Radiation Protective Devices-Part 1: Determination of Material Attenuation Performance* have been approved and are hereby promulgated.

(March 2, 2020)

国家药品监督管理局发布关于《医用诊断X射线辐射防护器具 第1部分：材料衰减性能的测定》等6项行业标准的公告

2020年3月5日，国家药品监督管理局发布关于《医用诊断X射线辐射防护器具 第1部分：材料衰减性能的测定》等6项行业标准的公告，内容如下：

YY／T 0292.1-2020《医用诊断X射线辐射防护器具 第1部分：材料衰减性能的测定》等6项医疗器械行业标准已经审定通过，现予以公布。（2020-03-02）

Annual Report

NMPA Issued the 2019 Annual Report for Medical Device Registration

On March 17, 2020, NMPA issued the *2019 Annual Report for Medical Device Registration*, which covers five parts: medical device registration status, medical device registration application acceptance status, medical device registration approval status, innovative medical device registration approval status, and other registration

年报

国家药品监督管理局发布《2019年度医疗器械注册工作报告》

2020年3月17日，国家药品监督管理局发布《2019年度医疗器械注册工作报告》，报告共有医疗器械注册工作情况、医疗器械注册申请受理情况、医疗器械注册审批情况、创新医疗器械等产品注册审批情况、其

management status.

● Acceptance of medical device registration applications

In 2019, NMPA has, as per its powers and duties, accepted a total of 9,104 applications for initial registration, registration renewals, and registration application for amendments of licensing matters of medical devices, a 37.8% increase as compared with that of 2018.

● Medical Device Registration Approval

In 2019, NMPA approved a grand sum of 8,471 registrations applications, up by 53.2% YOY, covering initial registrations (1,726), registration renewals (4,504), and registration alterations (2,241) of medical devices.

Note: The statistics period of this report is from January 1, 2019 to December 31, 2019.

(March 17, 2020)

他注册管理情况五个部分。

▪ 医疗器械注册申请受理情况

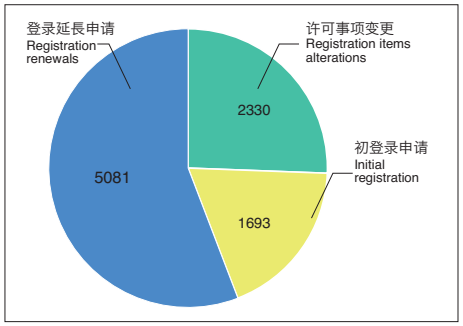
2019年，国家药品监督管理局依职责共受理医疗器械首次注册、延续注册和许可事项变更注册申请9104项，与2018年相比注册受理项目增加37.8%。

▪ 医疗器械注册审批情况

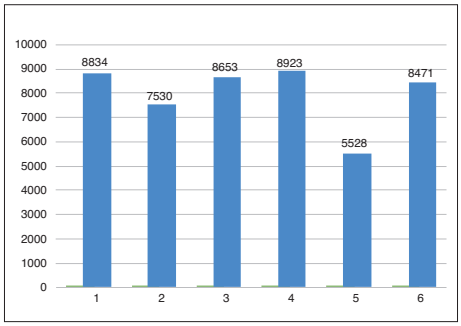
2019年，国家药品监督管理局共批准医疗器械首次注册、延续注册和变更注册8471项，与2018年相比注册批准总数量增长53.2%。其中，首次注册1726项，延续注册4504项，许可事项变更2241项。

注：本报告的数据统计自2019年1月1日至2019年12月31日。 （2020-03-17）

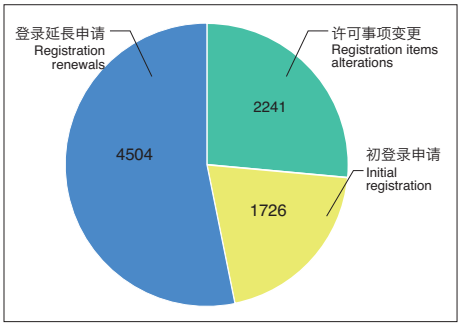
2019年注册受理项目注册形式比例图
Pie-chart of acceptances as per registration forms in 2019



2014至2019年度注册数据图
Registration data from 2014 to 2019



2019年注册形式比例图
Pie-chart of registration forms in 2019



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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