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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

Promulgation of the Rules for the Application of Discretion in Imposing Administrative Penalties in the Supervision and Administration of Medicinal Products

Recently, the Rules for the Application of Discretion in Imposing Administrative Penalties in the Supervision and Administration of Medicinal Products (hereinafter referred to as "Rules") were issued by China NMPA, which will come into force from August 1, 2024 onwards. The Rules for the Application of Discretion in Imposing Administrative Penalties in the Supervision and Administration of Medicinal Products and Medical Devices (SFDA [2012] No. 306) issued in 2012 are abolished at the same time.

The introduction of the Rules represents a significant step in implementing Xi Jinping's thought on the rule of law and modernizing the drug safety governance system and governance capacity. It also aims to fully implement the benchmark system of drug administrative discretion, and standardize the discretionary power of drug administrative penalties. In the process of formulating the Rules, the NPMA conducted exhaustive investigations, consultations, and demonstrations to strike an optimal balance between the general requirements for discretionary administrative penalties and the concrete demands of drug supervision and law enforcement. By seamlessly integrating these elements, the NPMA creates a framework that supports the scientific, systematic, and standardized application of the discretionary administrative penalties for drug supervision.

The Rules consist of six chapters and 54 articles, focusing on four aspects to improve the discretionary administrative penalties for drug supervision. Firstly, the discretionary circumstances have been improved. The criteria for aggravating, mitigating, withholding, exempting from punishment, and aggravating circumstances have been further refined. Additionally, in the context of drug supervision for first-time offenders and minor harm consequences, as specified in the Law of the People's Republic of China on Administrative Penalty, the specific meaning, determinants, and main factors for judgment have been clarified, responding to the high level of concern of various parties, including the drug regulatory departments at all levels, grass-roots law enforcement personnel, and enterprises. Secondly, the discretionary procedure has been standardized. The emphasis has been placed on ensuring that the discretionary procedure adheres to the principles of legal, comprehensive, and objective evidence collection, and the statements and pleadings of the parties should be fully heard, emphasizing the procedures of public hearing, collective discussions, and justification of discretion in accordance with the law. Thirdly, the principles for the formulation of the discretionary benchmarks have been clarified. The procedures and rules for formulating the discretionary benchmarks for drug penalties all over China have been further improved. The principles, requirements, and procedures for formulating the discretionary benchmarks have been standardized, ensuring that the criteria for determining fines, scope of penalties for individuals, and calculations of illicit profits are clearer and more comprehensive. Fourthly, discretionary oversight has been strengthened. Drug regulatory departments at all levels are required to implement a law enforcement accountability system and a fault accountability system, and establish and improve discretionary

头条

《药品监督管理行政处罚裁量适用规则》出台

日前，国家药监局发布《药品监督管理行政处罚裁量适用规则》(以下简称《裁量规则》)，自2024年8月1日起施行。2012年印发的《药品和医疗器械行政处罚裁量适用规则》（国食药监法〔2012〕306号）同时废止。

出台《裁量规则》是深入贯彻落实习近平法治思想，推进药品安全治理体系和治理能力现代化，全面推行药品行政裁量基准制度，规范药品行政处罚裁量权的重要举措。《裁量规则》在制定过程中经过深入调查研究、广泛征求意见、反复研究论证，在认真梳理行政处罚裁量一般要求的基础上，充分结合药品监管执法的实际需要，进一步提升药品监管行政处罚裁量适用的科学性、系统性和规范性。

《裁量规则》共六章五十四条，重点在四个方面对药品监管行政处罚裁量工作进行了完善。一是完善了裁量情形。进一步细化了从重、从轻、不予、免于处罚和情节严重的情形，对《行政处罚法》规定的初次违法、危害后果轻微，结合药品监管实际，明确了具体含义、认定情形、判定的主要因素，回应了各级药品监管部门、基层执法人员和企业等各方面的高度关注。二是规范了裁量程序。强化了裁量遵循依法、全面、客观取证原则，应充分听取当事人陈述和申辩，强调了依法举行听证、进行集体讨论、说明裁量理由等程序。三是明确了裁量基准制定的原则。进一步完善了各地药品处罚裁量基准的制定程序和规则，对制定裁量基准的原则、要求和程序作出规范，充实了罚款额度的确定、处罚到人的范围和违法所得的计算等内容。四是强化了裁量监督。要求各级药品监督管理部门落实执法责任制和过错责任追究制，建立健全行政处罚裁量监督机制，推进典型案例指导，及时纠正违法或明显不当行政处罚裁量基准或行为，持续规范行政处罚裁量权的行使。

《裁量规则》的制定和发布，对药品监管部门准确适用《行政处罚法》和药品监管"两法

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supervision mechanisms for administrative penalty. They must also promote typical case guidance, promptly address any illegal or blatantly improper administrative penalty discretionary benchmarks or behaviors, and continually standardize the exercise of administrative penalty discretion.

(February 23, 2024)

两条例”，指导基层执法人员严格规范公正文明执法，推进全国药品监管执法标准化、规范化、科学化，为企业营造公平正义的监管环境，具有重要意义。近期，国家药监局将组织开展《裁量规则》的系列宣贯培训，对全系统行政执法人员进行政策解读，指导各地认真贯彻落实，确保政策落地落实，切实规范药品监管行政处罚行为，保护公民、法人和其他组织的合法权益。

（2024-02-23）

Drugs

Innovative TCM Ercha Shangqing Wan Approved for Marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine (TCM) Ercha Shangqing Wan of Hubei Qijin Pharmaceutical Co., Ltd. was approved for marketing by China NMPA.

Randomized, double-blinded and placebo-controlled multicenter clinical trials had been conducted to evaluate the safety and efficacy of the medicine. The results showed that the group receiving the experimental medicine outperformed the placebo group in indicators of target ulcer healing rate, overall ulcer healing rate, overall ulcer healing time, and target ulcer healing time.

This medicine, with its properties of clearing heat, detoxifying the body, healing aphtha and relieving pain, is intended for the treatment of mild recurrent upper-jiao heat syndrome in patients with aphthous ulcers. The marketing of this medicine provides another treatment option for patients with oral ulcers.

(January 9, 2024)

药品

国家药监局批准中药创新药儿茶上清丸上市

近日，国家药品监督管理局批准了湖北齐进药业有限公司申报的中药1.1类创新药儿茶上清丸上市。

该药品开展了随机、双盲、安慰剂平行对照的多中心临床试验。临床试验研究结果显示，靶溃疡愈合率、所有溃疡愈合率、所有溃疡愈合时间、靶溃疡愈合时间等指标，试验组优于安慰剂组。

该药品清热退火、解毒敛疮、止痛，用于轻型复发性阿弗他溃疡上焦实热证。该药品的上市为口腔溃疡患者提供了又一种治疗选择。

（2024-01-09）

Lecanemab Injection Approved for Marketing by China NMPA

Recently, the Lecanemab Injection (trade name: 乐意保/Leqembi) of Eisai Inc. was approved for marketing by China NMPA through the priority review and approval procedures. It is indicated for the treatment of mild cognitive impairment and dementia caused by Alzheimer's disease.

The accumulation of amyloid beta (Aβ) plaques in the brain is one of the typical pathophysiological features of Alzheimer's disease. Lecanemab Injection is a humanized immunoglobulin IgG1 monoclonal antibody that directly antagonizes aggregated soluble and insoluble Aβ, thereby reducing Aβ plaques. The marketing of this drug provides a new treatment option for patients with Alzheimer's disease.

(January 9, 2024)

国家药监局批准仑卡奈单抗注射液上市

近日，国家药品监督管理局通过优先审评审批程序批准Eisai Inc.申报的仑卡奈单抗注射液（商品名：乐意保/Leqembi）上市。用于治疗由阿尔茨海默病引起的轻度认知障碍和阿尔茨海默病轻度痴呆。

脑内β淀粉样蛋白（Aβ）斑块积聚是阿尔茨海默病的典型病理生理特征之一。仑卡奈单抗注射液是一种人源化免疫球蛋白IgG1单克隆抗体，可直接拮抗聚集的可溶性和不溶性Aβ，从而减少Aβ斑块。该品种的上市为阿尔茨海默病患者提供了新的治疗选择。

（2024-01-09）

Ganagliflozin Proline Tablets Approved for Marketing by China NMPA

Recently, the Category 1 innovative product Ganagliflozin Proline Tablets (trade name: 惠优静) of Jilin Huisheng Biopharmaceutical Co,. Ltd. was approved for marketing by China NMPA. It is indicated to improve the blood sugar control for adult patients with type 2 diabetes by singe use or combined use with metformin hydrochloride.

The Ganagliflozin Proline Tablets is a sodium glucose co-transporter 2 (SGLT2) inhibitor that inhibits SGLT2, reduces the re-absorption of filtered glucose, lowers the renal threshold of glucose, and thus increases urine glucose excretion. The marketing of this drug provides a new treatment option for adult patients with type 2 diabetes.

(January 19, 2024)

国家药监局批准脯氨酸加格列净片上市

近日，国家药品监督管理局批准惠升生物制药股份有限公司申报的1类创新药脯氨酸加格列净片（商品名：惠优静）上市，该药适用于单药治疗或与盐酸二甲双胍联合使用，改善成人2型糖尿病患者的血糖控制。

脯氨酸加格列净是一种钠-葡萄糖协同转运蛋白2（SGLT2）抑制剂，通过抑制SGLT2，减少滤过葡萄糖的重吸收，降低葡萄糖的肾阈值，从而增加尿糖排泄。该药品的上市为成人2型糖尿病患者提供了新的治疗选择。

（2024-01-19）

Tegileridine Fumarate Injection Approved for Marketing by China NMPA

Recently, the Category 1 innovative product Tegileridine Fumarate Injection (trade name: 艾苏特) of Jiangsu Hengrui Pharmaceuticals Co., Ltd. was approved for marketing by China NMPA. It is indicated for moderate to severe pain after abdominal surgery.

Tegileridine Fumarate Injection is a complete opioid receptor agonists, which has relative selectivity on μ-opioid receptors (MOR) and is subject to the regulation of narcotic drugs. The marketing of this drug provides a new treatment option for patients with moderate to severe pain after abdominal surgery.

(January 31, 2024)

国家药监局批准富马酸泰吉利定注射液上市

近日，国家药品监督管理局批准江苏恒瑞医药股份有限公司申报的1类创新药富马酸泰吉利定注射液（商品名：艾苏特）上市，适用于腹部手术后中重度疼痛。

富马酸泰吉利定注射液是一种阿片受体完全激动剂,对阿片受体μ亚型(MOR)具有相对的选择性，按照麻醉药品管理。该药品的上市为腹部手术后中重度疼痛患者提供了新的治疗选择。

（2024-01-31）

Crovalimab Injection Approved for Marketing by China NMPA

Recently, the Crovalimab Injection (trade name: 派圣凯/Piasky) of Roche Pharma (Schweiz) AG was approved for marketing by China NMPA through the priority review and approval procedures. It is indicated for use in adults and adolescents (≥12 years old) with paroxysmal nocturnal hemoglobinuria who have not received complement inhibitor therapy.

The paroxysmal nocturnal hemoglobinuria (PNH) is a chronic intravascular hemolysis caused by blood cell membrane defect attributable to acquired hematopoietic stem cell gene mutations, which is often worsened during sleep, and can be accompanied by episodic hemoglobinuria, potential bone marrow failure, and thrombosis. The PNH has been included in the first batch of the rare diseases catalogue in China. The Crovalimab Injection is a recombinant humanized IgG1 subtype monoclonal antibody targeting complement protein C5. It can specifically bind to complement protein C5, thereby inhibiting C5 cleavage into C5a and C5b, preventing the production of terminal complement complex C5b-9, and therefore inhibiting the immune response of complement pathway. This drug variety has been in simultaneous global research and development and it is firstly approved for marketing in China, which provides new treatment options for patients.

(February 7, 2024)

国家药监局批准可伐利单抗注射液上市

近日，国家药品监督管理局通过优先审评审批程序批准Roche Pharma (Schweiz) AG申报的可伐利单抗注射液（商品名：派圣凯/Piasky）上市。用于未接受过补体抑制剂治疗的阵发性睡眠性血红蛋白尿症成人和青少年（≥12岁）患者。

阵发性睡眠性血红蛋白尿系获得性造血干细胞基因突变引起血细胞膜缺陷所致的慢性血管内溶血，常在睡眠时加重，可伴发作性血红蛋白尿、潜在的骨髓衰竭和血栓形成，已被纳入我国第一批罕见病目录。可伐利单抗注射液是一种靶向补体蛋白C5的重组人源化IgG1亚型单克隆抗体，能特异性地与补体蛋白C5结合，从而抑制C5裂解为C5a和C5b，阻止末端补体复合物C5b-9的产生，抑制补体途径免疫反应。该品种全球同步研发，中国首先批准上市，为患者提供了新的治疗选择。

（2024-02-07）

Innovative TCM Jiuwei Cough Syrup Approved for Marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine (TCM) Jiuwei Zhike Koufuye (cough syrup) of Zhuohe Pharmaceutical Group Co Ltd was approved for marketing by China NMPA.

Randomized, double-blinded, placebo- and positive-controlled multicenter clinical trials had been conducted to evaluate the safety and efficacy of the medicine. The results showed that the group receiving the experimental medicine outperformed the placebo group and was not inferior to the positive-controlled group in major indicators of cough disappearance rate and cough disappearance time.

This medicine, with its properties of clearing the lung and stopping a cough, is intended for the treatment of coughs in acute tracheitis and bronchitis diagnosed as wind-heat syndrome, a pattern of disharmony in TCM. The marketing of this TCM provides another treatment option for patients with a cough caused by acute tracheitis and bronchitis.

(February 21, 2024)

国家药监局批准中药创新药九味止咳口服液上市

近日，国家药品监督管理局批准了卓和药业集团股份有限公司申报的中药1.1类创新药九味止咳口服液上市。

该药品开展了随机、双盲、安慰剂及阳性药平行对照的多中心临床试验。临床试验研究结果显示，主要疗效指标：咳嗽消失率和咳嗽消失时间，试验组均优于安慰剂组、非劣效于阳性药组。

该药品宣肺止咳，用于急性气管-支气管炎中医辨证属风热证的咳嗽。该药品的上市为急性气管-支气管炎咳嗽患者提供了又一种治疗选择。

（2024-02-21）

Medical device

Gastric Bypass Stent System Approved for Marketing

Recently, the innovative product "Gastric Bypass Stent System" of Hangzhou Tongee Medical Technology Co., Ltd. was approved by China NMPA.

This product consists of a delivery system and a retrieval system. The delivery system includes a delivery device, a gastric bypass stent and a guide wire, with the gastric bypass stent pre-loaded into the storage tube of the delivery device. The retrieval system includes a retrieval tube, a retrieval hook and a retrieval cap. This product isolates the contact between chyme and intestinal tract. As an assisted lifestyle product for weight management during bypass, it is used for patients with obesity associated with ineffective lifestyle modification, poor response to non-invasive treatment and drug treatment.

This product is placed in the upper duodenum and jejunum assisted by gastroscope and can achieve the effect similar to gastric bypass without changing the physiological structure of gastrointestinal tract, reducing the absorption of nutrients in food by most tissues of duodenum and jejunum to achieve the purpose of weight loss, and providing a new option for the treatment of obesity.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(January 17, 2024)

医疗器械

胃转流支架系统获批上市

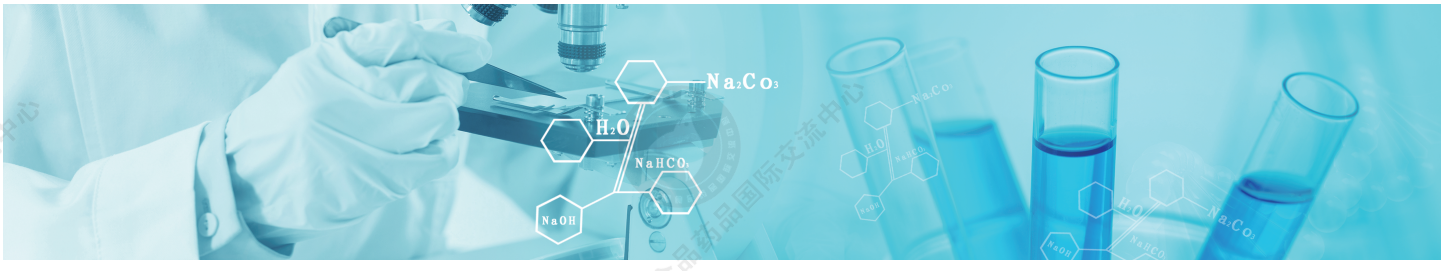
近日，国家药品监督管理局批准了杭州糖吉医疗科技有限公司"胃转流支架系统"创新产品注册申请。

该产品由输送系统和回收系统组成。输送系统由输送器、胃转流支架和导丝组成，胃转流支架预装在输送器的收纳管中。回收系统由回收管、回收钩和回收帽组成。该产品隔离食糜与肠道的接触，在转流期间作为一种辅助生活方式管理体重的产品，用于生活方式调整无效、无创治疗及药物治疗效果不佳的相关肥胖症患者。

该产品在胃镜辅助下置入十二指肠及空肠上段，在不改动胃肠道生理结构的基础上达到类似胃旁路手术的效果，减少十二指肠和空肠大部分组织对食物中营养成分的吸收，达到减重目的，为肥胖症治疗提供新的选择。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-01-17）



Reagents for Detection of Influenza A Viruses Approved by China NMPA

So far, China NMPA has approved a total of 66 reagents for detection of influenza A viruses, including 23 antigen detection products, 5 antibody detection products, and 38 nucleic acid detection products. Of the 66 products, 27 were single-use products and 39 were multi-use products, with most of the multi-use products detecting both influenza A and B viruses (see the attached table for details). Moving forward, China NMPA will persist in its diligent efforts to review and approve reagents for detection of influenza A viruses, catering to the pressing demands of the current infectious disease prevention and control landscape.

(January 19, 2024)

国家药监局已批准甲型流感病毒检测试剂情况

截至目前，国家药监局已批准甲型流感病毒检测试剂共66个，其中抗原检测产品23个、抗体检测产品5个、核酸检测产品38个。66个产品中，单检产品27个，联检产品39个，联检产品多为甲流、乙流联检（具体见附表）。下一步国家药监局将持续做好甲型流感病毒检测试剂审评审批工作，满足当前相关传染疫情防控需求。

（2024-01-19）

IFI44L Gene Methylation Detection Kit (PCR-Melting Curve Method) Approved for Marketing

Recently, the application for registration of innovative product "IFI44L Gene Methylation Detection Kit (PCR-Melting Curve Method)" of ShenZhen Sciarray Biotechnology Co., Ltd. was approved by China NMPA.

This product adopts PCR melting curve method to qualitatively detect the DNA methylation level of the promoter region of IFI44L (interferon (IFN)-induced protein 44-like) gene in human whole blood samples, and it can be used as an auxiliary diagnostic tool for systemic lupus erythematosus (SLE) combined with other indexes. This product, developed independently by China and boasting its own intellectual property rights, possesses the capability to diagnose patients with systemic lupus erythematosus prior to the occurrence of vital organ involvement, which is of great significance to the prevention and treatment of systemic lupus erythematosus, improvement of patients' quality of life, and enhancement of patients' survival rate.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(February 6, 2024)

IFI44L基因甲基化检测试剂盒(PCR-熔解曲线法)获批上市

近日，国家药品监督管理局批准了深圳市赛尔生物技术有限公司"IFI44L基因甲基化检测试剂盒（PCR-熔解曲线法）"创新产品注册申请。

该产品采用PCR熔解曲线法,对人体全血样本中IFI44L（干扰素诱导蛋白44L）基因启动子区域DNA甲基化水平定性检测，联合其它指标，可用于系统性红斑狼疮的辅助诊断。该产品由我国自主研发并拥有自主知识产权，可在系统性红斑狼疮患者出现重要器官受累前进行诊断，对于系统性红斑狼疮防治、改善患者的生活质量、提高患者生存率具有重要意义。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-02-06）

China Medical Device Standards Management Annual Report (2023)

I. Data overview of medical device standards

(i) Release data on formulation and revision plan of medical device standards

1. Formulation and revision plan of national standards. In 2023, the Standardization Administration approved and issued 52 national standard projects for medical devices, which were divided into formulation projects (34, 65.4%) and revision projects (18, 34.6%) according to the formulation and revision of standards; they were divided into mandatory standard projects (4, 7.7%), recommended standard projects (46, 88.5%), and guiding technical document projects (2, 3.8%) according to the nature of the standards.

2. Formulation and revision plan of industry standards. In 2023, China NMPA approved and issued 117 industry standard projects for medical devices, which were divided into formulation projects (57, 48.7%) and revision projects (60, 51.3%) according to the formulation and revision of standards; they were divided into mandatory standard projects (15, 12.8%) and recommended standard

中国医疗器械标准管理年报(2023年度)

一、医疗器械标准数据概览

（一）医疗器械标准制修订计划下达数据

1.国家标准制修订计划。2023年，国家标准委批准下达医疗器械国家标准立项计划52项，按照标准制修订划分，制定34项（占比65.4%），修订18项（占比34.6%）；按照标准性质划分，强制性标准计划4项（占比7.7%），推荐性标准计划46项（占比88.5%），指导性技术文件2项（占比3.8%）。

2.行业标准制修订计划。2023年，国家药监局批准下达医疗器械行业标准立项计划117

(ii) Data on issuance of approval of medical device standards

1. National standards. In 2023, the Standardization Administration approved and released 28 national standard projects for medical devices, which were divided into formulation projects (13, 46.4%) and revision projects (15, 53.6%) according to the formulation and revision of standards; they were divided into mandatory standard projects (5, 17.9%), recommended standard projects (21, 75.0%), and guiding technical document projects (2, 7.1%) according to the nature of the standards.

2. Industry standards. China NMPA approved and released 131 industry standard projects for medical devices, which were divided into formulation projects (68, 51.9%) and revision projects (63, 48.1%) according to the formulation and revision of standards; they were divided into mandatory standard projects (33, 25.2%) and recommended standard projects (98, 74.8%) according to the nature of the. 14 amendments to medical device industry standards were released.

(iii) Data on current medical device standards

1. Overall data on standards

As of December 31, 2023, China has a total of 1974 currently effective medical device standards, including 271 national standards and 1703 industry standards.

From 2019 to 2023, the number of national and industry standards has shown a steady upward trend year by year.

2. Data on standard category

According to the statistics of standardized objects, there were 330 basic standards (16.7%), 51 management standards (2.6%), 480 method standards (24.3%), and 1113 product standards (56.4%) in the currently effective medical device standards. In 2023, 25 basic standards (15.7%), 7 management standards (4.4%), 36 method standards (22.6%), and 91 product standards (57.3%) were issued.

According to the classification statistics specified in the Chinese Classification for Standards, the currently effective medical device standards comprehensively covered all technical fields of medical devices, mainly focusing on C44 Medical laboratory equipment (14.3%), C30 Medical apparatus and devices in general (11.3%), C35 Orthopedic devices (10.8%), and C31 General and microsurgical devices (10.4%). In 2023, the published standards covered 16 standard categories such as C30 Medical apparatus and devices in general, C33 Stomatologic device, equipment and material, etc. Medical apparatus and devices in general hold the distinction of having the largest number of published standards, accounting for 20.9% of the published standards in that year.

(iv) Data on standard technical organizations

In 2023, the Standardization Administration established the National Standardization Working Group for Medical Protective Devices (SAC/SWG30), China NMPA approved the establishment of the Standardized Technical Authorized Organization for Reliability and Maintainability of Medical Devices (SMD/TU009) and the Standardized Technical Authorized Organization for Oral Digitized Medical Devices (SMD/TU010), and approved the preparations for the establishment of the Standardized Technical Authorized Organization for the Standardization of Medical Device Packaging. As of December 31, 2023, there were a total of 38 medical device standard technical organizations, including 13 general standardization committees (TCs), 13 subcommittees for standards (SCs), 2 standardization working groups, and 10 technical authorized organizations.

II. Focus on medical device standards

(i) Solid foundation of standard system

In 2023, China NMPA took several measures to further standardize the approval and release of medical device standards. These efforts included the revision and issuance of the Working Rules for the Approval and Release of Medical Device Standards, as well as the organization of the Center for Medical Device Standardization Administration to formulate and issue the Principles for Determining National and Industry Standards for Medical Devices and Principles for Determining Mandatory Standards for Medical Devices to clarify the level and scope of standards. Additionally, China NMPA formulated and issued the Working Rules for the Evaluation of Medical Device Standard Implementation and the Feedback and Processing Mechanism for

项，按照标准制修订划分，制定57项（占比48.7%），修订60项（占比51.3%）；按照标准性质划分，强制性标准计划15项（占比12.8%），推荐性标准计划102项（占比87.2%），其中企业牵头标准项目22项（占比18.8%）。

（二）医疗器械标准批准发布数据

1.国家标准。2023年，国家标准委批准发布医疗器械国家标准28项，按照标准制修订划分，制定13项（占比46.4%），修订15项（占比53.6%）；按照标准性质划分，强制性标准5项（占比17.9%），推荐性标准21项（占比75.0%），指导性技术文件2项（占比7.1%）。

2.行业标准。国家药监局批准发布医疗器械行业标准131项，按照标准制修订划分，制定68项（占比51.9%），修订63项（占比48.1%）；按照标准性质划分，强制性标准33项（占比25.2%），推荐性标准98项（占比74.8%）。发布医疗器械行业标准修改单14项。

（三）现行医疗器械标准数据

1.标准总体数据

截至2023年12月31日，现行有效医疗器械标准共计1974项，其中国家标准271项，行业标准1703项。

2019年—2023年，国家标准和行业标准数量呈现逐年稳定上升趋势。

2.标准分类数据

按标准规范对象统计，现行有效的医疗器械标准中基础标准330项，占比16.7%；管理标准51项，占比2.6%；方法标准480项，占比24.3%；产品标准1113项，占比56.4%。2023年发布基础标准25项，占比15.7%；管理标准7项，占比4.4%；方法标准36项，占比22.6%；产品标准91项，占比57.3%。

按《中国标准文献分类法》分类统计，现行有效的医疗器械标准全面覆盖了医疗器械各技术领域，主要集中在医用化验设备C44（占比14.3%），医疗器械综合C30（占比11.3%），矫形外科、骨科器械C35（占比10.8%），一般与显微外科器械C31（占比10.4%）；2023年发布标准覆盖医疗器械综合C30、口腔科器械、设备与材料C33等16个标准类别，医疗器械综合类标准发布数量最多，占比达到当年发布标准的20.9%。

（四）标准技术组织机构数据

2023年，国家标准委成立全国医用防护器械标准化工作组（SAC/SWG30），国家药监局批准成立医疗器械可靠性与维修性标准化技术归口单位（SMD/TU009）和口腔数字化医疗器械标准化技术归口单位（SMD/TU010），批准筹建医疗器械包装标准化技术归口单位。截至2023年12月31日，医疗器械标准技

Medical Device Standard Opinions to solve the "problems faced in the final actual implementation" during standard implementation. Furthermore, China NMPA issued the Guidelines for Enterprises to Lead the Drafting of Recommended Industry Standards for Medical Devices (Trial) to outline the responsibilities and requirements for enterprises to take the lead in standard formulation and revision, with the goal of promoting the high-quality development of medical devices.

(ii) Constructing a three-dimensional support structure for the standard organization system

According to the counterparts with the International Organization for Standardization, China NMPA has taken steps to establish the National Technical Committee on Quality Management and General Requirements for Medical Device of Standardization Administration of China to set up the Working Group for Connectors for Liquid and Gas with Small Aperture and Liquid Receiver Delivery System for Medical Devices, and organized the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices to set up the Working Group for Additive Manufacturing of Implantable Devices, the Working Group for Ceramic Implantation, the Working Group for Implantation of Metallic Materials, and the Working Group for Implantation of Polymer Materials, etc., basically building up a three-dimensional structure of the standard organization system of medical devices with horizontal (general standardization committee, working group, authorized organization) to the edge, vertical (subcommittees for standards) to the end, vertical (standardization committee directly under the working group) support.

(iii) Establishing technical reserves for epidemic prevention and control standards in the new phase

In 2023, China NMPA paid close attention to the prevention and control of monkeypox virus, and organized the project application for the national standard of Quality Evaluation Requirements for Monkeypox Virus Nucleic Acid Detection Kits to regulate the production and quality control of monkeypox virus nucleic acid detection kits. China NMPA organized and carried out the translation of five national standards, including Quality Evaluation Requirements for COVID-19 Nucleic Acid Detection Kits, Quality Evaluation Requirements for COVID-19 Antibody Detection Kits, Quality Evaluation Requirements for COVID-19 IgG Antibody Detection Kits, Quality Evaluation Requirements for COVID-19 Antigen Detection Kits, and Quality Evaluation Requirements for COVID-19 IgM Antibody Detection Kits.

(iv) Comprehensive completion of the assessment and evaluation of the dual coverage of the standardization committee

(v) Enterprise-led industry standard formulation and revision continues to gain momentum

China NMPA launched an initiative to encourage enterprises to take the lead in drafting industry standards for medical devices. In 2023, the Guidelines for Enterprises to Lead the Drafting of Recommended Industry Standards for Medical Devices (Trial) were issued. As a result, 22 enterprise-led standard formulation and revision tasks were issued, marking the initial establishment of an enterprise-led, standardization committee-guided work mode in the medical device industry.

(vi) Standardizing the promotion of standard review and implementation evaluation

In 2023, China NMPA further strengthened the requirements for standard review and accelerated the construction of the standard implementation evaluation system. China NMPA completed the review of 942 current medical device standards and put forward the conclusions of the review; organized and executed an evaluation of the implementation of 45 typical standards, culminating in a detailed report on the implementation evaluation.

(vii) Establishing a mechanism for updating standards with rapid linkage to international standards

For international standards that are deemed appropriate for adaptation to China's unique national circumstances, we will closely monitor their development, conduct thorough research, and undertake synchronized transformations, ideally within a two-year window following the publication of the international standards. In 2023, a total of 66 international standards were incorporated into national and industrial

术组织共计38个，包括13个总标委会（TC）、13个分标委会（SC）、2个标准化工作组和10个技术归口单位。

二、医疗器械标准重点工作

（一）标准制度体系固本夯基

2023年国家药监局修订发布《医疗器械标准报批发布工作细则》，进一步规范医疗器械标准报批发布；组织器械标管中心制定印发《医疗器械国家标准和行业标准确定原则》《医疗器械强制性标准确定原则》，厘清标准层级和范围；制定印发《医疗器械标准实施评价工作细则》《医疗器械标准意见反馈及处理机制》，解决标准实施"最后一公里"问题；印发《企业牵头起草医疗器械推荐性行业标准工作规范（试行）》，明确企业牵头标准制修订职责要求，推动医疗器械高质量发展的标准制度体系进一步健全。

（二）构建标准组织体系立体支撑结构

根据国际标准化组织对口情况，组织全国医疗器械质量管理和通用要求标准化技术委员会组建医疗器械液体和气体用小孔径及贮液容器输送系统用连接件工作组，组织全国外科植入物和矫形器械标准化技术委员会组建增材制造植入器械标准工作组、植入陶瓷材料标准工作组、植入金属材料标准工作组、植入高分子材料标准工作组等4个工作组，基本构建起横向（总标委、工作组、归口单位）到边，纵向（分标委）到底，垂直（标委会直属工作组）支撑的医疗器械标准组织体系立体架构。

（三）做好新阶段疫情防控标准技术储备

2023年，密切关注猴痘病毒防控情况，组织提出《猴痘病毒核酸检测试剂盒质量评价要求》国家标准立项申请，规范猴痘病毒核酸检测试剂盒的生产和质量控制；组织开展《新型冠状病毒核酸检测试剂盒质量评价要求》《新型冠状病毒抗体检测试剂盒质量评价要求》《新型冠状病毒IgG抗体检测试剂盒质量评价要求》《新型冠状病毒抗原检测试剂盒质量评价要求》《新型冠状病毒IgM抗体检测试剂盒质量评价要求》等5项国家标准外文版翻译。

（四）全面完成标委会双覆盖考核评估

（五）企业牵头行业标准制修订接续发力

鼓励以企业为主体牵头起草医疗器械行业标准的积极性，2023年《企业牵头起草医疗器械推荐性行业标准工作规范（试行）》印发，并下达22项企业牵头标准制修订工作任务，企业牵头、标委会指导的工作模式初步确立。

（六）规范推进标准复审和实施评价

2023年国家药监局进一步强化标准复审工作要求，并加快推进标准实施评价体系建设。完成942项现行医疗器械标准复审，提出复

standards for medical devices, while 86 project plans for adapting international standards to China's national and industrial standards were approved and issued. As a result, the consistency level of international standards for medical devices exceeded 90%.

(viii) Accelerating the internationalization of medical device standards

In 2023, the international standard Aerosol bacterial retention test method for air-inlet filter on administration devices (standard No. ISO 24072:2023), which was developed by China, was officially released. Additionally, the international standard proposal Artificial intelligence enabled medical devices - Computer assisted analysis software for pulmonary images - Algorithm performance test methods (Project No. IEC 63524 ED1) was successfully established. Furthermore, six international standards were formulated and revised and the transformation of nine medical device standards into foreign languages has been progressing steadily. China's expertise in the field was recognized with the election of two Chinese experts as the Chairman of IEC SC 62B and the Vice-Chairman of IEC TC62. A total of 52 international standard meetings were organized, and 129 international standard votes were cast on behalf of China to participate in counterparts with the International Organization for Standardization. Moreover, 8 new experts registered with the International Organization for Standardization were added. The internationalization of medical device standards has been moving from integration to fusion.

(ix) Creating a positive social atmosphere for standardization

(x) Consistent standard service concepts

审结论；组织开展45项典型标准实施评价，形成实施评价工作报告。

（七）建立与国际标准快速联动的标准更新机制

对符合我国国情适合转化的国际标准，密切跟踪，提前研究，同步转化，原则上国际标准发布2年内转化。2023年已发布医疗器械国家、行业标准中采用国际标准的共66项，86项医疗器械国际标准转化为我国国家标准或行业标准的立项计划已批准下达，医疗器械国际标准一致性程度达90%以上。

（八）医疗器械标准国际化进程加快

2023年我国主导制定的国际标准《输液器具进气器件气溶胶细菌截留试验方法》（标准号ISO 24072:2023）正式发布，国际标准提案《人工智能医疗器械 肺部影像辅助分析软件 算法性能测试方法》（项目号IEC 63524 ED1）成功立项，6项国际标准制修订和9项医疗器械外文版标准转化工作稳步推进，推荐2名中国专家成功当选IEC SC 62B主席和IEC TC62副主席，组织参加国际标准会议共52次，代表我国参与对口国际标准化组织的国际标准投票129次，新增国际标准化组织注册专家8人，医疗器械标准国际化从融入走向融合。

（九）积极营造标准化良好社会氛围

（十）标准服务理念一以贯之

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- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
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