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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Drugs

Issuance of the 14th Five-Year Plan for National Drug Safety and High-Quality Development

Recently, 8 authorities including the National Medical Products Administration (NMPA) jointly issued the *14th Five-Year Plan for National Drug Safety and High-Quality Development* (hereinafter referred to as the *Plan*), which has clarified the guiding ideology for drug safety and promotion of high-quality development during the 14th Five-Year Plan period in China, put forward the overall principles of Five Adherences and main development goals, and formulated 10 main tasks, so as to guarantee drug safety, promote high-quality development of drugs, advance the modernization of drug regulatory system and capacity, and protect and promote public health during the 14th Five-Year Plan period.

The CPC Central Committee and the State Council attach great importance to drug regulation. General Secretary Xi Jinping has made a series of important instructions on drug regulation. The *Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives Through the Year 2035* calls for strict drug regulation, and make clear requirements for relevant practice.

According to the *Plan*, we shall hold the overall principles of Five Adherences, which is adherence to comprehensive CPC leadership, reform and innovation, scientific regulation, law-based supervision, and social co-governance, to accelerate China's transformation from a big pharmaceutical manufacturer to a pharmaceutical manufacturing power and better meet the health needs of the people.

The *Plan* defines the main development goals of the 14th Five-Year Plan period. By the end of the 14th Five-Year Plan period, the overall drug regulatory capacity will approach to the international advanced level, the level of drug safety and supply will continue to improve, and the public will become more satisfied and assured with the quality and safety of drugs. The regulatory environment to support high-quality development of the industry will be more optimized, the reform of evaluation and approval will be continuously deepened, a batch of innovative drugs in urgent clinical need will be approved, the marketing of innovative drugs with clinical value will be accelerated, the innovative drugs and medical devices in the world subject to registration application in China will be marketed within the territory of China as soon as possible, 2650 standards of drugs, medical devices and cosmetics will be formulated or revised, and 480 guidelines will be newly formulated; the vaccines regulation will reach the international advanced level, by passing the assessment of national regulatory system for vaccines by the World Health Organization, and we will actively promote that the drug inspection and testing institutions of the provinces where vaccine manufacturers are located have the lot release capacity for main varieties of vaccines manufactured within the jurisdiction; new progress will be made in the inheritance and innovative development of traditional Chinese medicine (TCM), the evaluation evidence system with the combination of TCM theories, experience in human application and clinical trials will be preliminarily established, the safety evaluation methods and standard system meet the TCM characteristics will be gradually explored and established, and the modern regulatory system of TCM will be further improved; great progress will be made in the development of professional talent team, a

药品

“十四五”国家药品安全及促进高质量发展规划印发

日前，国家药监局等8部门联合印发《“十四五”国家药品安全及促进高质量发展规划》（以下简称《规划》），明确了我国“十四五”期间药品安全及促进高质量发展的指导思想，提出五个“坚持”总体原则和主要发展目标，并制定出10个方面主要任务，以保障“十四五”期间药品安全，促进药品高质量发展，推进药品监管体系和监管能力现代化，保护和促进公众健康。

党中央、国务院高度重视药品监管工作。习近平总书记就做好药品监管工作作出了一系列重要指示批示。《中华人民共和国国民经济和社会发展第十四个五年规划和2035年远景目标纲要》提出严格药品监管，并就有关工作作出明确要求。

《规划》提出，要把握坚持党的全面领导、坚持改革创新、坚持科学监管、坚持依法监管、坚持社会共治五个“坚持”的总体原则，加快推动我国从制药大国向制药强国跨越，更好满足人民群众的健康需求。

《规划》明确了“十四五”时期主要发展目标，“十四五”期末，药品监管能力整体接近国际先进水平，药品安全保障水平持续提升，人民群众对药品质量和安全更加满意、更加放心。支持产业高质量发展的监管环境更加优化，审评审批制度改革持续深化，批准一批临床急需的创新药，加快有临床价值的创新药上市，在中国申请的全球创新药、创新医疗器械尽快在境内上市，制修订药品医疗器械化妆品标准2650项（个），新增指导原则480个；疫苗监管达到国际先进水平，通过世界卫生组织疫苗国家监管体系评估，积极推进疫苗生产企业所在省级药品检验机构具备辖区内生产疫苗主要品种批签发能力；中药传承创新发展迈出新步伐，中医药理论、人用经验和临床试验相结合的审评证据体系初步建立，逐步探索建立符合中药特点的安全性评价方法和标准体系，中药现代监管体系更加健全；专业人才队伍建设取得较大进展，培养一批具备国际先进水平的高层次审评员、检查员和检验检测领域专业

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number of senior evaluators and inspectors with international advanced level as well as academic leaders with excellent professional competence in the field of inspection and testing will be cultured, the professional competence of drug regulators will be significantly improved, and positive results will be achieved in the development of the professional team; the technical support capacity will be significantly enhanced, the full life-cycle pharmacovigilance system will be preliminarily established, positive results will be achieved in the Action Plan for Drug Regulatory Science in China, and the capacities of drug inspection and testing institutions will be significantly improved.

According to the development goals, the *Plan* proposed 10 main tasks, including implementing the whole-process regulation of drug safety, supporting the industrial upgrade and development, improving the drug safety governance system, continuously deepening the reform of evaluation and approval system, conducting strict vaccines regulation, promoting the inheritance and innovative development of TCM, strengthening the capacity building of technical support, enhancing the building of professional talent team, enhancing the smart regulatory system and capacity building, and enhancing the emergency system and capacity building.

Meanwhile, the *Plan* proposes 10 key construction projects in the form of special columns, including the action plan for screening drug safety risks, the action plan for improving national drug standards, multi-sectoral coordination policy toolkit for drug safety governance, acceleration of evaluation and approval system building, improvement of national ADR monitoring system, inspection and testing capacity improvement project, promotion of the building of key laboratory of regulatory science, professional competence improvement project, smart regulation project, and emergency capacity improvement project.

The *Plan* focuses on the building of professional capacities in evaluation, inspection, testing, monitoring and reevaluation and talent team, and takes the building of drug regulatory system and capacity as the important contents. In addition to "ensuring the safety and safeguarding the bottom line", the Plan proposes the measures for "promoting development and pursuing high line" and promoting high-quality development of drugs.

The *Plan* calls for strengthening the overall coordination and leadership of drug safety, innovating and improving the support and guarantee mechanism, actively participating in global drug safety governance, and encouraging drug regulators to fulfill their duties and responsibilities. Local governments at all levels shall take the overall responsibility for drug safety within their regions, and all provincial people's governments shall establish a drug safety coordination mechanism to make an overall planning for drug safety and economic and social development.

(December 30, 2021)

素质过硬的学科带头人，药品监管队伍专业素质明显提升，队伍专业化建设取得积极成效；技术支撑能力明显增强，全生命周期药物警戒体系初步建成，中国药品监管科学行动计划取得积极成果，药品检验检测机构能力明显提升。

根据“十四五”发展目标，《规划》提出了实施药品安全全过程监管、支持产业升级发展、完善药品安全治理体系、持续深化审评审批制度改革、严格疫苗监管、促进中药传承创新发展、加强技术支撑能力建设、加强专业人才队伍建设、加强智慧监管体系和能力建设、加强应急体系和能力建设10方面主要任务。

同时，《规划》以专栏形式提出药品安全风险排查行动计划、国家药品标准提高行动计划、药品安全治理多部门协同政策工具箱、加快审评审批体系建设、完善国家药品不良反应监测系统、检验检测能力提升工程、推进监管科学重点实验室建设、专业素质提升工程、智慧监管工程、应急能力提升项目10个重点建设项目。

《规划》重点突出审评、检查、检验、监测评价以及队伍建设等专业化能力建设，将药品监管体系和监管能力建设作为重要内容。在“保安全守底线”的同时，《规划》还提出“促发展追高线”、促进药品高质量发展的工作措施。

《规划》要求，要加强对药品安全工作的统筹协调领导，创新完善支持保障机制，积极参与全球药品安全治理，激励药品监管干部队伍履职尽责担当作为。地方各级政府对本地区药品安全工作负总责，各省级人民政府要建立药品安全协调机制，统筹药品安全和经济社会发展。 (2021-12-30)

NMPA and Hainan Province Jointly Promoted the Pilot Application of Clinical Real-World Data of Drugs and Devices

On December 28, 2021, the NMPA and the Hainan Province jointly convened the third meeting of the leading group on the pilot application of clinical real-world data of drugs and devices in 2021, to summarize the experience in the pilot application of clinical real-world data and discuss new measures to further promote real-world studies to contribute to the high-quality development of the biomedical industry and the reform of the evaluation and approval system for drugs and medical devices in Hainan Free Trade Port. Wang Bin, Vice Governor of Hainan Province, and Xu Jinghe, Deputy Commissioner of NMPA, attended and addressed at the meeting.

In 2021, NMPA and the Hainan Province have worked together to actively carry out the study and exploration on the collection

国家药监局和海南省政府共同推进药械临床真实世界数据应用试点相关工作

2021年12月28日，国家药监局和海南省政府联合召开2021年药品医疗器械临床真实世界数据应用试点工作领导小组第三次会议，总结临床真实世界数据应用试点工作经验，共商深入推进真实世界研究新举措，助力海南自贸港生物医药产业高质量发展和药品医疗器械审评审批制度改革。海南省副省长王斌、国家药监局副局长徐景和出席会议并讲话。

of real-world evidence and its application in regulatory decision making. Multiple guidelines related to clinical real-world study of drugs and medical devices have been successively issued, research base for drug and medical device regulatory science and key laboratory for real-world study and evaluation in Hainan have been set up and operated, and pilot varieties of drugs and medical devices, such as femtosecond laser system and pralsetinib capsules, have been successively approved for marketing with real-world study data of Boao Lecheng as auxiliary clinical evaluation evidences. The management of drugs and medical devices in urgent clinical need for import has been further regulated, and progress has been made in the trial application of clinical real-world data.

Also, in-depth discussions were conducted in the meeting on further deepening the reform of drug and medical device evaluation and approval system, innovating the drug and medical device regulatory mode of Hainan Free Trade Port, implementing the action plan for drug regulatory science, and exploring new tools, methods and means for the study and application of real-world data.

The meeting was held in the form of videoconferencing, and attended by leaders of relevant departments as well as directly affiliated institutions of NMPA, leaders of relevant departments of Hainan Province, and members of the Expert Working Group.

(December 28, 2021)

2021年，国家药监局和海南省政府通力合作，积极开展真实世界证据采集和用于监管决策的研究探索，多个药品医疗器械临床真实世界研究相关指导原则陆续发布，海南药品医疗器械监管科学研究基地、真实世界研究与评价重点实验室成立运行，飞秒激光眼科治疗系统、普拉替尼胶囊等药品医疗器械试点品种利用博鳌乐城真实世界研究数据作为辅助临床评价证据先后获批上市。临床急需进口药品医疗器械管理进一步规范，临床真实世界数据应用试点工作取得了阶段性成果。

会议同时对进一步深化药品医疗器械审评审批制度改革、创新海南自贸港药品医疗器械监管模式、贯彻落实药品监管科学行动计划以及探索真实世界数据研究应用新工具、新方法、新手段等内容进行了深入研讨。

会议以视频方式进行，国家药监局有关司局及直属单位负责人，海南省委省政府有关厅局负责人及专家工作组成员参加会议。

(2021-12-28)

NMPA held a working conference on the TCM quality and safety regulation

On December 29, NMPA held a working conference on the TCM quality and safety regulation to comprehensively summarize relevant work in 2021, deeply analyze current regulatory situation and matters, and deploy the priorities in 2022 to continuously enhance the TCM quality and safety regulation. Zhao Junning, Member of NMPA Leading Party Members' Group and NMPA Deputy Commissioner, attended and addressed at the meeting.

In 2021, NMPA thoroughly implemented the decisions and deployments of the CPC Central Committee and the State Council on promoting the inheritance and innovative development of TCM, strictly implemented the Four Strictest requirements, strengthen the TCM quality and safety regulation for epidemic prevention and control, and effectively guarantee the quality and supply of TCM. NMPA continuously improved the development of laws, regulations, institutions and systems for TCM, studied and introduced policies for TCM decoction pieces manufacturers to purchase freshly cut Chinese crude drugs, guided the standardized development of Chinese crude drugs, and accelerated the revision of Good Agricultural Practice (GAP); promoted special rectification of TCM decoction pieces, achieved effective results to be achieved in the special rectification of TCM decoction pieces and the special inspection on TCM production, organized targeted unannounced inspections, and enhance sampling inspections and ADR monitoring. Drug regulatory authorities strictly implemented the territory regulatory responsibilities, strictly investigated and dealt with cases of violation of laws and regulations in the TCM production, urged enterprises to effectively fulfill their principal responsibilities, promoted the successful completion of various objectives and tasks of the supervision over TCM quality and safety regulation, and achieved steady improvement of the overall TCM quality.

Zhao Junning fully affirmed the achievement made in the TCM quality and safety regulation in 2021. He stressed that it is necessary to accurately grasp the new situation, new tasks and new challenges,

国家药监局召开中药质量安全监管工作会议

12月29日，国家药监局召开中药质量安全监管工作会议，全面总结2021年中药质量安全监管工作，深入分析当前监管形势与问题，研究部署2022年重点工作，持续强化中药质量安全监管。国家药监局党组成员、副局长赵军宁出席会议并讲话。

会议指出，2021年，国家药监局深入贯彻落实党中央、国务院关于促进中医药传承创新发展等决策部署，严格落实“四个最严”要求，加强疫情防控用中药的质量安全监管，有效保障质量和供应。不断完善中药监管法规制度体系建设，研究出台中药饮片生产企业购买趁鲜切制中药材的政策，引导中药材规范化发展，加快推进《中药材生产质量管理规范》（GAP）修订。推动中药饮片专项整治、中药生产专项检查取得实效，组织开展有针对性的飞行检查，强化抽检和不良反应监测。药品监管部门严格落实属地监管责任，严厉查处中药生产环节违法违规案件，督促企业切实落实主体责任，推动中药质量安全监管各项目标任务圆满完成，推进中药整体质量持续稳中向好。

赵军宁充分肯定了2021年中药上市后质量安全监管工作成绩。他强调，要准确把握当前中药质量安全监管面临的新形势、新任

systematically think, make overall plan, be innovative and responsible, orderly promote the reform of TCM regulatory system, strengthen the TCM quality and safety regulation, and promote the high-quality development of TCM.

The NMPA shall consolidate the TCM quality and safety regulation in 2022. The first is to continuously strengthen the regulation over prepared slices of Chinese crude drugs and TCM preparations for epidemic prevention and control, provide technical guidance and other services, and support TCM to continue to play an important role in regular epidemic prevention and control to safeguard the overall situation of epidemic prevention and control. The second is to accelerate the issuance and implementation of newly revised GAP, orderly promote manufactures of prepared slices of Chinese crude drugs to purchase freshly cut Chinese crude drugs, guide and promote the standardized development of Chinese crude drugs, and promote the TCM quality from the source. The third is to practicably supervise the TCM formula granules, implement strict access for products and enterprises, adhere to the scientificity of TCM formula granules, execute strict regulation over the complete production capacity, prohibit from loosening requirements in a disguised form such as sharing a workshop within the group, carry out the inspection with a full overage of the production and sampling inspection on all varieties, and urge enterprises to ensure product quality and safety. The fourth is to focus on enhancing the supervision over the quality of prepared slices of Chinese crude drugs and TCM preparations, continuously organize special inspections and causal inspections, strengthen sampling inspections and ADR monitoring, strengthen the regulation over the whole chain including production, circulation and use, enhance organic connection between inspections and investigation, and severely crack down on violations of laws and regulations. The fifth is to comprehensively improve the capacity and level of TCM regulation, actively promote the "coordination of nation as in a chess game", vigorously promote the research of TCM regulatory science, actively play the role of "smart regulation", constantly meet the needs of the TCM quality and safety regulation in the new era, and effectively ensure the safety and effective use of drugs by the people.

The meeting was held in the form of videoconferencing. Representatives of 7 provinces (regions) including Anhui, Jiangxi, Gansu, Shandong, Xinjiang, Jiangsu and Guangdong made speeches on the special rectification of prepared slices of Chinese crude drugs, the special inspection on the TCM production and the unannounced inspection on TCM. Leaders of relevant departments as well as directly affiliated institutions of NMPA, leaders of the medical products administration of all provinces (autonomous regions, municipalities) and Xinjiang Production and Construction Corps in charge of the TCM quality and safety regulation, relevant departments and relevant persons in charge of drug inspection institutions participated in the meeting.

(December 31, 2021)

务和新挑战，系统思考、统筹谋划，勇于创新、敢于担当，有序推进中药监管制度改革，强化中药质量安全监管，促进中药高质量发展。

药品监管部门要扎实做好2022年中药质量安全监管。一要持续加强疫情防控用中药饮片、中成药监管，做好技术指导等服务，支持中医药在常态化疫情防控中继续发挥重要作用，保障疫情防控大局。二要加快推进新修订GAP的发布实施，有序推进中药饮片生产企业采购趁鲜切制中药材，引导促进中药材规范化发展，从源头上促进中药质量。三要切实做好中药配方颗粒监管，严格产品、企业准入，坚持中药配方颗粒科学性，严格把关完整的生产能力，不得以集团内部共用车间等方式变相放宽要求，要开展生产全覆盖检查、全品种抽检，督促企业切实保障产品质量安全。四要重点强化中药饮片、中成药质量监管，持续组织专项检查、有因检查，强化抽检和不良反应监测，加强生产、流通、使用等全环节监管，加强检查稽查有机衔接，严厉打击违法违规行为。五要综合提升中药监管能力和水平，积极推进构建“全国一盘棋”格局，大力推进中药监管科学研究，积极发挥“智慧监管”作用，不断满足新时代中药质量安全监管工作需要，切实保障人民群众用药安全有效。

会议以视频方式举行。安徽、江西、甘肃、山东、新疆、江苏、广东7个省（区）药监局代表就中药饮片专项整治、中药生产专项检查及中药飞行检查等工作进行交流发言。国家药监局相关司局和直属单位有关负责人，以及各省（区、市）、新疆生产建设兵团药监局负责中药质量安全监管工作局领导、相关处室及药品检查机构的相关负责人参会。

（2021-12-31）

Notice of the Center for Drug Evaluation of NMPA on Issues related to the Implementation of ICH Guideline M9: Biopharmaceutics Classification System-Based Biowaivers and Q&A Document thereof

According to the NMPA Announcement, in order to well implement the ICH Guideline M9: Biopharmaceutics Classification System-Based Biowaivers and Q&A Document thereof (hereinafter referred to as M9 Guideline), upon the approval by National Medical Products Administration, the CDE is hereby notifying relevant issues as follows:

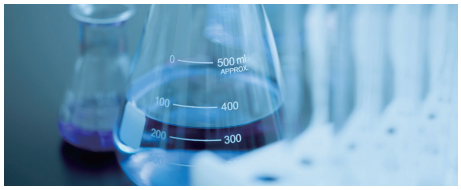
I. If M9 requirements are met according to the assessment by the applicant, the

国家药监局药审中心关于实施国际人用药品注册技术协调会指导原则《M9：基于生物药剂学分类系统的生物等效性豁免》及问答文件有关事项的通知

根据国家药品监督管理局公告，为做好国际人用药品注册技术协调会指导原则《M9：基于生物药剂学分类系统的生物等效性豁免》及问答文件（以下简称M9指导原则）的实施工作，经国家药品监督管理局

applicant can directly propose exemption of human bioequivalence test in the drug registration application. NMPA will not issue a separate catalogue of varieties exempted from human bioequivalence test or subject to simplified human bioequivalence test.

II. Applying for exemption from human bioequivalence tests shall be indicated in the application form. If the exemption cannot be made after evaluation, and the substantial defects cannot be corrected, the applicant will not be required to provide supplementary materials, and the registration application shall be disapproved.



III. In case of inconsistency between the previously issued *Guideline for Exemption from Human Bioequivalence Tests* and the M9 Guideline, the M9 Guideline shall prevail.

IV. The study data related to the exemption from human bioequivalence tests shall be submitted uniformly according to Module 5.3.1.2 of the current edition of M4: Organization of the Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use. The contents of application dossiers routinely required remain unchanged.

(December 31, 2021)

同意，药审中心现就有关事项通知如下：

一、经申请人评估认为符合M9指导原则要求的，申请人可以直接在药品注册申请中提出豁免人体生物等效性试验，国家药监局不再单独发布可豁免或简化人体生物等效性试验品种目录。

二、申请豁免人体生物等效性试验的，需在申请表中予以注明。经审评不能豁免，且属于实质性缺陷无法补正的，不再要求申请人补充资料，注册申请不予批准。

三、原发布的《人体生物等效性试验豁免指导原则》与M9指导原则不一致的，以M9指导原则为准。

四、人体生物等效性试验豁免相关的研究资料按照现行版《M4：人用药物注册申请通用技术文档（CTD）》模块5.3.1.2项下统一提交。常规要求的申报资料内容保持不变。

（2021-12-31）

Notice of the Center for Drug Evaluation of NMPA on the Applicability of E2B (R3) Regional Implementation Guide to Individual Case Safety Reports during Drug Clinical Trials

In order to implement the *E2B (R3) Regional Implementation Guide for Individual Case Safety Reports* (hereinafter referred to as the Regional Implementation Guide), the Center for Drug Evaluation has completed the upgrade of the pharmacovigilance system during clinical trials, which was put into trial operation on January 1, 2022. Applicants shall complete the system configuration in a timely manner, and implement E2B (R3) in accordance with the Regional Implementation Guide no later than July 1, 2022.

Regional field test requirements:

I. Users who have previously passed the test

The users who have previously passed the test shall generate a test ICSR in XML format that meets the requirements of the Regional Implementation Guide and email it to E2Btest@cde.org.cn, with the email subject indicating "Application for China regional field test of E2B (R3)-enterprise name"; the email text shall provide the sponsor name and the unique ID of the enterprise (N.2.r.2), and list the specific regional fields tested and the allowable values.

II.Users who have not passed the test yet

The users who have not passed the test yet shall apply for the test on the basis of meeting relevant requirements in the *Standard and Procedure for Rapid Reporting of Safety Data during Drug Clinical Trials* and with reference to the above test requirements.

(January 5, 2022

国家药监局药审中心关于药物临床试验期间个例安全性报告适用E2B(R3)区域实施指南的通知

为实施《个例安全性报告E2B(R3)区域实施指南》（以下简称区域实施指南），药审中心已完成对临床试验期间药物警戒系统升级改造，已于2022年1月1日上线试运行。申请人应及时完成系统配置,并按照区域实施指南要求实施E2B (R3)，时间不得晚于2022年7月1日。

区域字段测试要求：

一、原通过测试用户

原通过测试用户需生成一份符合区域实施指南要求的XML格式的测试ICSR并发送至E2Btest@cde.org.cn，邮件主题标明“申请E2B(R3) 中国区域字段测试–企业名称”，正文提供申办者名称、企业的唯一识别ID(N.2.r.2)、列出所测试的具体区域字段及允许值。

二、尚未通过测试用户

尚未通过测试用户需在符合《药物临床试验期间安全性数据快速报告标准和程序》相关要求的基础上，参照上述测试要求申请测试。

（2022-01-05）

NMPA Announcement on the *Technical Guideline for the Revision of Safety Information Items in Package Inserts of Marketed Traditional Chinese Medicines (Interim)*

In order to further guide drug marketing authorization holders to revise the safety information items in package inserts of marketed traditional Chinese medicines, strengthen life cycle management of traditional Chinese medicines and guarantee the drug safety for the public, NMPA organized to formulate the *Technical Guideline for the Revision of Safety Information Items in Package Inserts of Marketed Traditional Chinese Medicines (Interim)*, which was issued on January 4, 2022. (January 7, 2022)

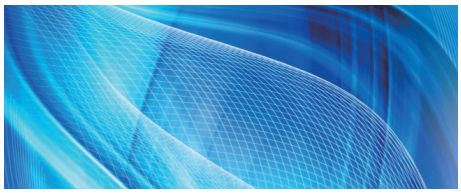
国家药监局关于发布《已上市中药说明书安全信息项内容修订技术指导原则（试行）的通告

为进一步指导药品上市许可持有人对已上市中药说明书安全信息项内容的修订，加强中药全生命周期管理，保障公众用药安全，国家药监局组织制定了《已上市中药说明书安全信息项内容修订技术指导原则（试行）》，于2022年1月4日发布。（2022-01-07）

Medical Devices

NMPA Announcement on the *Emergency Approval Procedure for Medical Devices*

In order to effectively prevent, timely control and eliminate the hazards of public health emergencies and ensure that the approval of medical devices required for emergency response to public health emergencies can be completed as soon as possible, according to the *Regulations for the Supervision and Administration of Medical Devices* (State Council Order No.739), *Provisions for the Registration and Filing of Medical Devices* (SAMR Order No.47) and *Provisions for the Registration and Filing of In Vitro Diagnostic Reagents* (SAMR Order No.48), National Medical Products Administration organized to revise the *Emergency Approval Procedure for Medical Devices*, which is issued and take effect as of December 29, 2021. The *Notice on Printing and Issuing the Emergency Approval Procedure for Medical Devices* issued by the former China Food and Drug Administration (CFDA [2009] No.565) shall be abolished at the same time. (December 29, 2021)



医疗器械

国家药监局关于发布《医疗器械应急审批程序》的公告

为有效预防、及时控制和消除突发公共卫生事件的危害，确保突发公共卫生事件应急所需医疗器械尽快完成审批，根据《医疗器械监督管理条例》（国务院令第739号）及《医疗器械注册与备案管理办法》（市场监管总局令第47号）、《体外诊断试剂注册与备案管理办法》（市场监管总局令第48号），国家药品监督管理局组织修订了《医疗器械应急审批程序》，于2021年12月29日发布并施行。原国家食品药品监督管理局《关于印发医疗器械应急审批程序通知》（国食药监械〔2009〕565号）同时废止。（2021-12-29）

NMPA Announcement on Two Guidelines for Registration Review of Drug-Device Combination Products with Device Taking Primary Mode of Action

In order to enhance the regulation and guidance for the registration of drug-device combination products, further encourage the marketing of drug-device combination products with clinical value, and build a management mode for drug-device combination products suitable for China's national conditions, National Medical Products Administration has set the technical evaluation of drug-device combination products as a research project in regulatory science, and organized to formulate the *Guideline for Registration Review Drug-Device Combination Products with Device Taking Primary Mode of Action* and the *Guideline for Registration Review of Qualitative, Quantitative and In Vitro Release Studies of Drugs in Drug-Device Combination Products with Device Taking Primary Mode of Action*, which were issued on January 11, 2022. *(January 17, 2022)*

国家药监局关于发布以医疗器械作用为主的药械组合产品等2项注册审查指导原则的通告

为加强对药械组合产品注册工作的监督和指导，进一步鼓励具有临床价值的药械组合产品上市，构建适合我国国情的药械组合产品的管理模式，国家药品监督管理局将药械组合产品技术评价作为监管科学研究项目，组织制定了《以医疗器械作用为主的药械组合产品注册审查指导原则》《以医疗器械作用为主的药械组合产品中药物定性定量及体外释放研究注册审查指导原则》，于2022年1月11日发布。（2022-01-17）

Cosmetics

NMPA Announcement on Trial Operation of Electronic Registration Certificate for Cosmetics

In order to implement the decisions and deployment of the CPC Central Committee and the State Council on deepening the reform to "Streamline Administration, Delegate Power, Strengthen Regulation and Improve Services", optimize the business environment, further stimulate the development vitality of market entities, and provide enterprises with more efficient and convenient government services, it has been decided upon study that electronic registration certificate for cosmetics will start trial operation since January 1, 2022. Relevant issues are hereby announced as follows:

I. From January 1, 2022, electronic registration certificate will be issued to special cosmetics and new cosmetic ingredients with application submitted and approved for registration according to the *Provisions for the Registration and Filing of Cosmetics*.

II. From May 1, 2022, electronic registration certificate will be issued to special cosmetics approved of change or renewal of registration.

III. Electronic and paper registration certificates have the same legal effect. The electronic certificate has such functions as instant service, SMS reminder, certificate authorization, QR code verification, online verification and whole network sharing. Registrants shall correctly use and properly keep the electronic registration certificate. Answers for frequently asked questions on electronic certificates can be found in the "Frequently Asked Questions for Electronic Certificates" at the Online Service Hall.

IV. During the trial operation, electronic and paper registration certificates will be issued simultaneously. When the paper registration certificate for special cosmetics and new cosmetic ingredients is issued, the electronic registration certificate will be automatically pushed to the space of its legal representative at the Online Service Hall for the registrants (persons in charge within the territory of China). Registrants (persons in charge within the territory of China) shall first register and authenticate with their real names at the NMPA Online Service Hall, enter the Column of "My Certificates" at the Online Service Hall, view and download the electronic registration certificate of cosmetics, or log in NMPA APP to view and download the electronic registration certificate.

V. The time for official implementation of electronic registration certificate for cosmetics will be announced separately.

(December 27, 2021)

化妆品

国家药监局关于试行化妆品电子注册证的公告

为贯彻落实党中央、国务院关于深化“放管服”改革的重要决策部署，优化营商环境，进一步激发市场主体发展活力，为企业提供更加高效便捷的政务服务，经研究决定，自2022年1月1日起，试行化妆品电子注册证。现将有关事项公告如下：

一、自2022年1月1日起，按照《化妆品注册备案管理办法》提出申请并获准注册的特殊化妆品和化妆品新原料，开始发放电子注册证。

二、自2022年5月1日起，特殊化妆品获准注册证变更、延续的，开始发放电子注册证。

三、电子注册证与纸质注册证具有同等法律效力。电子证照具有即时送达、短信提醒、证书授权、扫码验真、在线验证、全网共享等功能，注册人应当正确使用和妥善保管电子注册证。常见电子证照问题解答可查看网上办事大厅“电子证照常见问题解答”栏目。

四、试行期间，电子注册证与纸质注册证并行发放。特殊化妆品和化妆品新原料纸质注册证发放的同时，电子注册证将自动推送至注册人（境内责任人）网上办事大厅的法定代表人空间。注册人（境内责任人）须先行在国家药监局网上办事大厅注册并实名认证，进入网上办事大厅“我的证照”栏目，查看下载化妆品电子注册证。也可登录“中国药监APP”，查看下载电子注册证。

五、正式实施化妆品电子注册证的时间，另行公告。

（2021-12-27）

NMPA Announcement on the *Good Manufacturing Practice for Cosmetics*

In order to regulate the production quality management of cosmetics, according to the *Regulations for the Supervision and Administration of Cosmetics, Provisions for the Supervision and Administration of Cosmetics Manufacture and Distribution* and other laws, regulations and rules, NMPA organized to formulate the *Good Manufacturing Practice for Cosmetics* (hereinafter referred to as the *GMP*), which was issued on January 6, and shall enter into force as of July 1, 2022.

From July 1, 2022, registrants, filing applicants and entrusted manufacturers of

国家药监局关于发布《化妆品生产质量管理规范》的公告

为规范化妆品生产质量管理，根据《化妆品监督管理条例》《化妆品生产经营监督管理办法》等法规、规章，国家药监局组织制定了《化妆品生产质量管理规范》（以下简称《规范》），于1月6日公布，自2022年7月1日起施行。

自2022年7月1日起，化妆品注册人、备案人、受托生产企业应当按照《规范》要求组织生产化妆品。2022年7月1日前已取得化

cosmetics shall organize the production of cosmetics in accordance with the *GMP* requirements. Enterprises that have obtained the cosmetics production licenses before July 1, 2022 and need to upgrade their factory facilities and equipment and other hardware conditions shall complete the upgrade before July 1, 2023, to ensure their factory facilities and equipment meet the *GMP* requirements. (January 7, 2022)

妆品生产许可的企业，其厂房设施与设备等硬件条件须升级改造的，应当自2023年7月1日前完成升级改造，使其厂房设施与设备等符合《规范》要求。 (2022-01-07)

NMPA Notice on Launching the Cosmetic Ingredient Safety Information Registration Platform

In order to implement the *Provisions for the Registration and Filing of Cosmetics, Provisions for the Registration or Filing Dossier of Cosmetics* and other regulatory documents, NMPA organized to establish the Cosmetic Ingredient Safety Information Registration Platform. Since 9 A.M. on December 31, 2021, cosmetic ingredient manufacturers or their authorized enterprises can log in to this platform to report information related to the safety of ingredients. Domestic users may log in to the platform directly through the "Cosmetic Ingredient Safety Information Registration Platform" module at NMPA Online Service Hall (https://zwfw.nmpa.gov.cn); and overseas users need to set up an account at the "Cosmetic Ingredient Safety Information Registration Platform" (http://ciip.nifdc.org.cn) before login.

After the launch of the Cosmetic Ingredient Safety Information Registration Platform, cosmetics registrants, filing applicants and persons in charge within the territory of China can still fill out and submit the safety information document of ingredients issued by raw material manufacturers through the Information Service Platform for Registration and Filing of Cosmetics, or fill in the safety information document of ingredients associated with the ingredients submission code generated by the platform.

(December 30, 2021)

国家药监局关于化妆品原料安全信息登记平台上线的通知

为贯彻落实《化妆品注册备案管理办法》《化妆品注册备案资料管理规定》等法规文件，国家药监局组织建立了化妆品原料安全信息登记平台，自2021年12月31日上午9时起，化妆品原料生产商或其授权企业可以登陆该平台报送原料安全相关信息。其中，境内用户直接通过国家药监局网上办事大厅（https://zwfw.nmpa.gov.cn）的"化妆品原料安全信息登记平台"模块进行登陆；境外用户需在"化妆品原料安全信息登记平台"（http://ciip.nifdc.org.cn）开通账号后登陆。

化妆品原料安全信息登记平台上线后，化妆品注册人、备案人、境内责任人仍可以通过化妆品注册备案信息服务平台填报原料生产商出具的原料安全信息文件，也可以填写化妆品原料安全信息登记平台生成的原料报送码关联原料安全信息文件。

(2021-12-30)

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
• For electronic version of the Newsletter please visit http://www.ccfdie.org

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。
• 电子版Newsletter阅览请登录网站http://www.ccfdie.org

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