NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Drugs

Meeting held to step up preparations for NRA assessment

The NMPA held a meeting on March 14 in preparation for the National Regulatory Authority (NRA) assessment of vaccines by the World Health Organization. NMPA Deputy Commissioner Zhao Junning attended the meeting and delivered a speech.

It was noted at the meeting that the Communist Party of China Central Committee and the State Council have always attached great importance to vaccine safety. The NRA assessment of vaccines is a comprehensive evaluation of the national vaccine regulatory capacity and level. It is a task that concerns national honor, the Chinese drug regulator's image and public health. It serves as a foundation for Chinese vaccine products to be used abroad and is also a work priority for the NMPA.

In 2021, all preparations for the assessment were carried out in an all-around way and achieved good results. All related departments and provincial-level administrations, under the leadership of the NMPA, have steadily pushed forward relevant preparations and successfully completed the WHO's remote mid-term assessment.

The meeting also called for more endeavors to continuously improve the vaccine regulatory quality management system and ensure the consistency of the vaccine regulatory systems. It also put emphasis on cross-departmental and cross-regional cooperation and information disclosure to ensure coordination of relevant sub-indicators of each sector.

In terms of current problems and challenges, it is important to carefully analyze causes and accelerate rectification and improvement. Efforts should be made not only to pass the assessment, but also to lay a solid foundation for the modernization of China's vaccine regulatory system and capacity in the long run.

Zhao said all preparations for the WHO's official assessment in June 2022 have entered the final sprint. All of the departments and provincial-level administrations should promote relevant work with a high sense of responsibility to comprehensively demonstrate China's vaccine regulatory capacity and level.

It is necessary to ensure collaboration between all departments and efficiently keep work on schedule and pay close attention to indicator requirements and opinions of WHO experts to fill in gaps. Provincial-level administrations responsible for on-site assessments should carry out drills in advance and concentrate on details. A complete national regulatory system, unified quality management standards and rigorous and orderly operation status should be prepared before the assessment. At the same time, the NMPA and all provincial-level administrations should continue to strengthen supervision and inspection of vaccines, enhance construction of inspector teams and continuously elevate vaccine regulatory capacity and level, he said.

The meeting was held both online and offline. Members of the NMPA NRA assessment leadership group and working group, officials of the National Health Commission and the Chinese Center for Disease Control and Prevention participated in the meeting on site. Officials

药品

疫苗国家监管体系评估工作推进会议召开

3月14日，国家药监局召开迎接世界卫生组织疫苗国家监管体系（NRA）评估工作推进会议，总结前期工作情况，深入分析当前形势，部署迎接正式评估相关工作。国家药监局党组成员、副局长赵军宁出席会议并讲话。

党中央、国务院一直以来高度重视疫苗安全。疫苗NRA评估是对国家疫苗监管能力和水平的全面评价，是一项事关国家荣誉、药监形象、公众健康的政治任务，是疫苗产品走出国门的基础，也是国家药监局的重点工作。

会议指出，2021年，疫苗NRA评估的各项准备工作全面展开，取得较好效果。在国家药监局统一指挥下，各部门、各省局稳步推进相关准备工作，顺利完成世卫组织远程中期评估。会议要求，要持续完善疫苗检查质量管理体系，确保疫苗监管体系的一致性；要关注跨部门、跨地区的共同协作；要持续加强信息公开；要做好各板块关联亚指标的协调一致。针对当前工作中存在的问题和挑战，要认真分析原因，推进整改完善，既要确保顺利通过正式评估，更要立足长远，为不断推进我国疫苗监管体系和监管能力现代化夯实基础。

赵军宁强调，今年7月我国将迎来世卫组织的正式评估，现在距正式评估还有4个月，迎评工作到了冲刺阶段。各部门、各省局要提高政治站位、强化责任担当，以高度的使命感和责任心推动各项相关工作，全面展示我国的疫苗监管能力和水平。要在现有工作专班基础上进一步强化组织保障，与相关部门密切配合、倒排工期、挂图作战，高效推动迎评准备工作。要紧盯指标要求和世卫组织评估专家意见，做好查缺补漏。承担现场评估工作的相关省局要提前开展演练，抓实抓细现场评估各环节工作准备。各部门、各省局要落实相关责任和任务分工，以完整的国家监管体系、统一的质量管理标准和严谨有序的运行状态迎接正式评估。同时，国家局和各省局要持续加强疫苗监督检查工作，落实疫苗监管责任，不断加强检查员队伍建设，持续提升疫苗监管能力和水平，确保顺利通过。

会议以线上线下相结合的方式进行。国家

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of provincial-level administrations and members of working groups in Beijing, Tianjin, Liaoning, Jilin, Shanghai, Zhejiang, Anhui, Fujian, Shandong, Henan, Hubei, Sichuan and Yunnan attended the meeting online.

(March 15, 2022)

药监局疫苗NRA评估工作领导小组成员和工作小组成员，国家卫健委疾控局、中国疾控中心相关人员在主会场参会。北京、天津、辽宁、吉林、上海、浙江、安徽、福建、山东、河南、湖北、四川、云南等省局主要负责同志和工作专班成员在分会场参会。 （2022-3-15）

NMPA Announcement on Issuing the Catalogue of Reference Preparations of Generic Drugs (Fiftieth Batch)

On January 7, 2022, the NMPA issued the Catalogue of Reference Preparations of Generic Drugs (Fiftieth Batch), which has been reviewed and determined by the NMPA Experts Committee of Quality and Efficacy Consistency Evaluation of Generic Drugs.

(January 11, 2022)

国家药监局关于发布仿制药参比制剂目录（第五十批）的通告

经国家药品监督管理局仿制药质量和疗效一致性评价专家委员会审核确定，国家药监局于2022年1月7日发布仿制药参比制剂目录（第五十批）。 （2022-01-11）

The designation of IBPC of NIFDC, NMPA as the WHO Collaborating Center on the standardization and evaluation of biologicals has been successfully renewed

The designation of the Institute for Biological Products Control (IBPC) of National Institutes for Food and Drug Control (NIFDC) as the WHO Collaborating Center on the standardization and evaluation of biologicals has been successfully renewed, with the term of designation from December 24, 2021 to December 24, 2025. The IBPC has been designated for two consecutive terms since 2013. During the terms, the IBPC has successfully completed various activities in the work plan, including supporting WHO in developing and revising international standards for biologicals, contributing to the development of international standards and reference materials for biologicals, conducting research & development of quality control assays for biologicals, and providing technical assistance in vaccine prequalification, which has been highly recognized by relevant WHO management departments and officials.

(January 11, 2022)

国家药监局中检院生检所成功续任世界卫生组织生物制品标准化和评价合作中心

中检院生物制品检定所续任WHO生物制品标准化和评价合作中心，任期为2021年12月24日至2025年12月24日。生检所自2013年被指定为WHO生物制品标准化和评价合作中心，已连任两期。任期内，该中心根据职能范围圆满完成了任务书中的各项工作计划，包括支持WHO生物制品标准制修订、推动国际生物标准物质研制、研究建立生物制品质量控制新方法和为疫苗预认证提供技术支持等，得到了WHO相关管理部门和官员的高度肯定。 （2022-01-11）

NMPA Announcement on Further Strengthening the Administration of Radioactive Pharmaceuticals

In order to further strengthen the manufacturing management of radioactive pharmaceuticals and ensure their quality, safety and effectiveness, in accordance with the *Drug Administration Law, Provisions for the Administration of Radioactive Pharmaceuticals* and other laws and regulations, the relevant issues are hereby announced as follows on January 13, 2022:

I. The test of three consecutive batches of labeled radioactive pharmaceuticals has been adjusted to be done after a manufacturer has obtained the Production License for radioactive pharmaceuticals, and may be carried out simultaneously in combination with the dynamic production batch for GMP conformity inspection. The sample testing should be undertaken

国家药监局关于进一步加强放射性药品管理有关事宜的通告

为进一步加强放射性药品生产管理，保证放射性药品质量安全有效，根据《药品管理法》《放射性药品管理办法》等法律法规，于2022年1月13日将有关事宜通告如下：

一、 即时标记放射性药品连续三批样品检验调整至生产企业取得放射性药品生产许可证后进行，可结合药品生产质量管理规

by drug testing institutions that meet the *Provisions for the Administration of Radioactive Pharmaceuticals*.

II. For the filing of a medical institution for the preparation of positron radioactive pharmaceuticals, the test of three consecutive batches of samples of the variety to be manufactured and the review of the quality standard should be undertaken by drug testing institutions that meet the *Provisions for the Administration of Radioactive Pharmaceuticals*.

III. Marketing authorization holders and manufacturers of radioactive pharmaceuticals and medical institutions preparing positron radioactive pharmaceuticals should be equipped with quality control and inspection personnel with professional knowledge related to radioactive pharmaceuticals, and such personnel should receive trainings adapted to the requirements of the post and be qualified in the assessment before taking up the position.

IV. Marketing authorization holders and manufacturers of radioactive pharmaceuticals and medical institutions preparing positron radioactive pharmaceuticals should earnestly fulfill the principal responsibility for drug quality management and strictly carry out quality control and inspection throughout the whole process of manufacturing. Products can be sold and used only after passing the quality tests.

V. Drugs containing radionuclides with a short half-life may be inspected while being released from the factory. However, in case of identifying any drug with the quality failing to meet the national drug standards, the marketing authorization holder and the manufacturer should immediately stop the manufacturing and sale, notify end users to stop the use, and take corresponding risk control measures.

VI. The provincial drug regulatory departments should strengthen the in- and post-process supervision, further strengthen the supervision and inspection of the manufacturing process of radioactive pharmaceuticals, urge radioactive pharmaceutical manufacturers and medical institutions to fulfill the principal responsibility for the quality and safety of radioactive pharmaceuticals, and ensure that the whole process of radioactive pharmaceutical manufacturing continuously meets the legal requirements.

VII. This Announcement should take effect as of the date of issuance. In case of any discrepancy between the provisions previously issued by the drug regulatory department under the State Council and this Announcement, this Announcement shall prevail. (January 14, 2022)

范符合性检查的动态生产批同步开展。样品检验由符合《放射性药品管理办法》相关规定的药品检验机构承担。

二、 医疗机构制备正电子类放射性药品备案时，拟生产品种的连续三批样品检验以及质量标准复核由符合《放射性药品管理办法》相关规定的药品检验机构承担。

三、放射性药品上市许可持有人、放射性药品生产企业以及制备正电子类放射性药品的医疗机构应当配备具有放射性药品相应专业知识的质量控制和检验人员，相关人员须接受与岗位要求相适应的培训并考核合格方可上岗。

四、药品上市许可持有人、药品生产企业以及制备正电子类放射性药品的医疗机构应当切实落实药品质量管理主体责任，严格实行生产全过程的质量控制和检验。质量检验合格的产品方可销售或使用。

五、含有短半衰期放射性核素的药品，可以边检验边出厂。但发现质量不符合国家药品标准时，药品上市许可持有人和药品生产企业应当立即停止生产、销售，通知使用单位停止使用，并采取相应的风险管控措施。

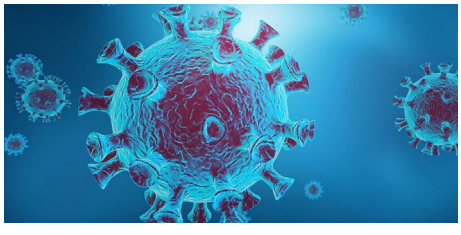
六、各省级药品监管部门应当加强事中事后监管，进一步加强放射性药品生产过程的监督检查，督促放射性药品生产企业和医疗机构落实放射性药品质量安全主体责任，确保药品生产全过程持续符合法定要求。

七、本通告自印发之日起执行，此前国务院药品监管部门发布的规定与本通告不一致的，以本通告为准。

(2022-01-14)

Announcement of the Center for Drug Evaluation of NMPA on Issuing the *Technical Guidance for Clinical Trials of New Antiviral Drugs for COVID-19 (Interim)*

In order to guide the scientific research, development and evaluation of antiviral drugs for COVID-19 and provide technical standards for reference, the CDE has formulated the *Technical Guidance for Clinical Trials of New Antiviral Drugs for COVID-19 (Interim)*. According to the requirements of the *Notice of the NMPA Comprehensive Department on Printing and Issuing the Release Procedures for Drug Technical Guidance*, the Guidance was issued for implementation on February 8, 2022 upon review and approval by NMPA. (February 17, 2022)



国家药监局药审中心关于发布《新型冠状病毒肺炎抗病毒新药临床试验技术指导原则（试行）》的通告

为指导新型冠状病毒肺炎抗病毒药物的科学研发和评价，提供可供参考的技术标准，药审中心制定了《新型冠状病毒肺炎抗病毒新药临床试验技术指导原则（试行）》。根据《国家药监局综合司关于印发药品技术指导原则发布程序的通知》要求，经国家药品监督管理局审查同意，于2022年2月8日发布并施行。 (2022-02-17)

Notice of the National Center for ADR Monitoring Center of NMPA on Issuing the Guidance for the Preparation of Master Files of Pharmacovigilance System

In order to implement the principal responsibilities of drug marketing authorization holders and pharmacovigilance main body responsibility and guide drug marketing authorization holders to create and maintain master files of pharmacovigilance system, the National Center for ADR Monitoring has formulated the *Guidance for the Preparation of Master Files of Pharmacovigilance System* in accordance with the requirements of the National Medical Products Administration, which was issued on February 25, 2022.

(February 25, 2022)

国家药监局国家药品不良反应监测中心关于发布药物警戒体系主文件撰写指南的通知

为落实药品上市许可持有人药物警戒主体责任，指导药品上市许可持有人创建和维护药物警戒体系主文件，按照国家药品监督管理局要求，国家药品不良反应监测中心组织制定了《药物警戒体系主文件撰写指南》，于2022年2月25日发布。（2022-02-25）

Announcement of NMPA and General Administration of Customs on the Establishment of Aidian Port as a Crude Drug Import Port

According to the *Drug Administration Law of the People's Republic of China*, upon the approval of the State Council, it is agreed to establish Aidian Port, Chongzuo City, Guangxi Zhuang Autonomous Region (hereinafter referred to as Aidian Port) as a crude drug import port. The relevant issues are hereby announced as follows:

I. Crude drugs can be imported through Aidian Port from March 10, 2022. All imported crude drugs should comply with the *Provisions for Crude Drug Importation* and other relevant provisions.

II. Chongzuo Administration for Market Regulation of Guangxi Zhuang Autonomous Region shall be the drug regulatory department corresponding to Aidian Port, and shall undertake the filing of imported crude drugs at Aidian Port from March 10, 2022, organize port inspection and conduct supervision and administration.

III. Guangxi Institute for Food and Drug Control, the drug inspection institution corresponding to Aidian Port, should undertake the crude drug port inspection at Aidian Port from March 10, 2022.

(March 16, 2022)

国家药监局 海关总署关于增设广西壮族自治区崇左市爱店口岸为药材进口边境口岸的公告

根据《中华人民共和国药品管理法》，经国务院批准，同意增设广西壮族自治区崇左市爱店口岸（以下简称爱店口岸）为药材进口边境口岸。现将有关事项公告如下：

一、自2022年3月10日起，药材可经由爱店口岸进口。所进口药材应符合《进口药材管理办法》等有关规定。

二、广西壮族自治区崇左市市场监督管理局为爱店口岸对应的口岸药品监督管理部门，2022年3月10日起，开始承担爱店口岸进口药材的备案，组织口岸检验并进行监督管理工作。

三、广西壮族自治区食品药品检验所为爱店口岸对应的口岸药品检验机构，自2022年3月10日起，开始承担爱店口岸的药材口岸检验工作。（2022-03-16）

Announcement of the National Medical Products Administration, Ministry of Agriculture and Rural Affairs, National Forestry and Grassland Administration, and National Administration of Traditional Chinese Medicine on Issuing the Good Agricultural Practice for Chinese Crude Drugs

In order to implement the *Opinions of the CPC Central Committee and the State Council on Promoting the Inheritance, Innovation and Development of Traditional Chinese Medicine*, promote the regulated manufacturing of Chinese crude drugs, strengthen the quality control of Chinese crude drugs, and promote the high-quality development of traditional Chinese medicine, the National Medical Products Administration, Ministry of Agriculture and Rural Affairs, National Forestry and Grassland Administration, and National Administration of Traditional Chinese Medicine formulated the Good Agricultural Practice (hereinafter referred to as the GAP) in accordance with the *Drug Administration Law of the People's Republic of China* and *Law of the People's Republic of China on Traditional Chinese Medicine*, which was

国家药监局 农业农村部 国家林草局 国家中医药局关于发布《中药材生产质量管理规范》的公告

为贯彻落实《中共中央 国务院关于促进中医药传承创新发展的意见》，推进中药材规范化生产，加强中药材质量控制，促进中药高质量发展，依据《中华人民共和国药品管理法》《中华人民共和国中医药法》，国家药监局、农业农村部、国家林草局、国家中医药局研究制定了《中药材生产质量管理规范》（以下称本规范），于2022年3月1日发布实施，并将有关事项公告如下：

promulgated and implemented on March 1, 2022, and the relevant issues are hereby announced as follows:

I. The GAP is applicable to the whole process management of regulated manufacturing of Chinese crude drugs by Chinese crude drugs manufacturers, and is the basic requirement of regulated manufacturing and management of Chinese crude drugs. The Chinese crude drugs in the GAP refer to the medicinal raw materials derived from medicinal plants, medicinal animals and other resources and used for the manufacturing of prepared slices of Chinese crude drugs and preparations after standardized planting (including ecological planting, wild cultivation and imitated wild cultivation), breeding, harvesting and processing in the manufacturing place.

Chinese crude drugs manufacturers in this announcement include planting and breeding specialized cooperatives or cooperatives with the nature of an enterprise.

II. Manufacturers of prepared slices of Chinese crude drugs, marketing authorization holders of Chinese patent medicine are encouraged to build or jointly build manufacturers and manufacturing bases of Chinese crude drugs at the place of origin of Chinese crude drugs in accordance with the GAP, and extend the drug quality management system to the place of origin of Chinese crude drugs.

TCM manufacturers are encouraged to give priority to the use of Chinese crude drugs that meet the GAP requirements. Where there are explicit requirements in the drug approval documents, TCM manufacturers should use the Chinese crude drugs that meet the GAP requirements according to the provisions. Relevant TCM manufacturers should carry out supplier audit according to law and conduct audit and inspection in accordance with the GAP requirements to ensure the compliance with the requirements.

III. For the use of Chinese crude drugs that meet the GAP requirements, the relevant TCM manufacturers can refer to the relevant provisions on drug label management, mark the information “crude drugs meet the GAP requirements” at the appropriate position of the drug label, and promote it according to law. For TCM compound preparations, all the ingredients in the formula should meet the GAP requirements before marked with "meet GAP requirements".

Provincial drug regulatory departments should strengthen supervision and inspection, and when necessary, may carry out extended inspection on the corresponding TCM manufacturers that should use or mark the use of Chinese crude drugs that meet the GAP, with emphasis on whether they meet the GAP or not. In case of identifying any inconformity, the drug regulatory departments shall conduct severe investigation and punishment according to law, order the TCM manufacturer to make rectification within a prescribed time limit, cancel the labeling, etc., and disclose the information of corresponding manufacturers of Chinese crude drugs and their varieties of Chinese crude drugs, and notify the people's government of the place of origin of Chinese crude drugs.

IV. Under the leadership of the provincial Party Committee and the provincial government, the relevant administrative departments of each province should cooperate with and assist the people's government of the place of origin of Chinese crude drugs to achieve regulated development of Chinese crude drugs, such as improving the working mechanism for high-quality development of Chinese crude drugs industry; formulating the development plan for Chinese medicine materials industry; refining the incentive policies to promote the regulated development of Chinese crude drugs; establishing a standing book and credit archives for TCM manufacturers and their manufacturing bases to implement dynamic supervision; and establishing an information platform for regulated manufacturing and traceability for Chinese crude drugs. Provinces with a better basis for regulated and intensive manufacturing of Chinese crude drugs are encouraged to study and formulate implementation rules based on the actual development of Chinese crude drugs in the areas under their jurisdiction, and make active exploration and promotion, so as to accumulate experiences for further promotion of the GAP.

一、本规范适用于中药材生产企业规范生产中药材的全过程管理，是中药材规范化生产和管理的基本要求。本规范涉及的中药材是指来源于药用植物、药用动物等资源，经规范化的种植（含生态种植、野生抚育和仿野生栽培）、养殖、采收和产地加工后，用于生产中药饮片、中药制剂的药用原料。

本公告所指中药材生产企业包括具有企业性质的种植、养殖专业合作社或联合社。

二、鼓励中药饮片生产企业、中成药上市许可持有人等中药生产企业在中药材产地自建、共建符合本规范的中药材生产企业及生产基地，将药品质量管理体系延伸到中药材产地。

鼓励中药生产企业优先使用符合本规范要求的中药材。药品批准证明文件等有明确要求的，中药生产企业应当按照规定使用符合本规范要求的中药材。相关中药生产企业应当依法开展供应商审核，按照本规范要求进行审核检查，保证符合要求。

三、使用符合本规范要求的中药材，相关中药生产企业可以参照药品标签管理的相关规定，在药品标签中适当位置标示“药材符合GAP要求”，可以依法进行宣传。对中药复方制剂，所有处方成份均符合本规范要求，方可标示。

省级药品监督管理部门应当加强监督检查，对应当使用或者标示使用符合本规范中药材的中药生产企业，必要时对相应的中药材生产企业开展延伸检查，重点检查是否符合本规范。发现不符合的，应当依法严厉查处，责令中药生产企业限期改正、取消标示等，并公开相应的中药材生产企业及其中药材品种，通报中药材产地人民政府。

四、各省相关管理部门在省委省政府领导下，配合和协助中药材产地人民政府做好中药材规范化发展工作，如完善中药材产业高质量发展工作机制；制定中药材产业发展规划；细化推进中药材规范化发展的激励政策；建立中药材生产企业及其生产基地台账和信用档案，实施动态监管；建立中药材规范化生

V. The relevant administrative departments of each province should conduct inspection and provide technical guidance on the implementation and promotion of the GAP according to their responsibilities. Relevant authorities of Ministry of Agriculture and Rural Affairs should take the lead in providing guidance on the supply of seeds, seedlings and provenances of Chinese crude drugs, field management, use of pesticides and fertilizers, and pest control. Relevant authorities of the National Forestry and Grassland Administration should take the lead in providing guidance on ecological planting, wild cultivation and imitated wild cultivation of Chinese crude drugs, as well as planting and breeding of Chinese crude drugs under the management category of endangered plants. TCM regulatory authorities should work together to provide guidance on seeds and seeding, standardized planting, harvesting and processing, and ecological planting of Chinese crude drugs. The drug regulatory departments should carry out extended inspections on the corresponding manufacturers of Chinese crude drugs, and provide guidance on the requirements for medicinal use, processing in the place of origin and quality inspection.

VI. The relevant administrative departments of each province should strengthen cooperation to form a joint force, jointly promote the regulated, standardized and intensive development of Chinese crude drugs, enhance publicity and training according to their responsibilities, and promote the implementation of the GAP. The relevant administrative departments of each province should strengthen the routine supervision during the implementation. In case identifying any major problems or suggestions on the improvement of major policies, please report to the corresponding management department of the State in time. (March 17, 2022)

产追溯信息化平台等。鼓励中药材规范化、集约化生产基础较好的省份，结合本辖区中药材发展实际，研究制定实施细则，积极探索推进，为本规范的深入推广积累经验。

五、各省相关管理部门依职责对本规范的实施和推进进行检查和技术指导。农业农村部门牵头做好中药材种子种苗及种源提供、田间管理、农药和肥料使用、病虫害防治等指导。林业和草原部门牵头做好中药材生态种植、野生抚育、仿野生栽培，以及属于濒危管理范畴的中药材种植、养殖等指导。中医药管理部门协同做好中药材种子种苗、规范种植、采收加工以及生态种植等指导。药品监督管理部门对相应的中药材生产企业开展延伸检查，做好药用要求、产地加工、质量检验等指导。

六、各省相关管理部门应加强协作，形成合力，共同推进中药材规范化、标准化、集约化发展，按职责强化宣传培训，推动本规范落地实施。加强实施中日常监管，如发现存在重大问题或者有重大政策完善建议的，请及时报告国家相应的管理部门。（2022-03-17）

The 4th Asian Network Meeting was held

On the afternoon of April 6, 2022, the 4th Asian Network Meeting was held online. Heads of national medical products regulatory authorities of China, India, Indonesia, Japan, the Republic of Korea, Malaysia, Myanmar, the Philippines, Singapore, Vietnam and Thailand exchanged views on regulatory cooperation against the pandemic in Asia, construction of a pharmaceutical ecosystem in Asia, and improvement of the accessibility and affordability of medicines. Xu Jinghe, Vice Commissioner of the China NMPA, attended the meeting and delivered a speech.

Mr. Xu said that the Asian Network Meeting provides an important communication platform for medical products regulatory authorities in Asia to continuously focus on regulatory issues with common characteristics of the Asian region and facilitate the development of medical products regulatory capacity in Asia with a broad vision. In recent years, medical products regulatory authorities in China have been adhering to the people-centered philosophy of development, adhering to the lofty mission of protecting and promoting public health, adhering to the scientific, legalized, international and modernized development path, continuously deepening the reform of drug and medical device review and approval system, continuously advancing the development and marketing as well as quality supervision of drugs and medical device products for pandemic prevention and control, continuously carrying out medical products regulatory scientific research, and continuously enhancing the construction of the medical products regulatory system and regulatory capacity, and the medical products regulatory reform and innovation has embarked on a new journey, creating a new situation. We look forward to further deepening exchanges and cooperation between regulatory authorities

第四届亚洲监管网络会议召开

2022年4月6日下午，第四届亚洲监管网络会议（Asian Network Meeting）在线召开。中国、印度、印度尼西亚、日本、韩国、马来西亚、缅甸、菲律宾、新加坡、越南、泰国国家药品监管机构负责人，就亚洲地区抗击疫情监管合作、亚洲药品生态体系建设、提升药品的可及性和可负担性等方面开展交流。国家药品监督管理局副局长徐景和出席会议并致辞。

徐景和表示，亚洲监管网络会议为亚洲各国药品监管机构提供了重要的交流沟通平台，持续关注具有亚洲区域共同特点的监管问题，以宽广的视野助力亚洲地区药品监管能力发展。近年来，中国药品监管部门坚持以人民为中心的发展思想，坚持保护和促进公众健康的崇高使命，坚持科学化、法治化、国际化、现代化的发展道路，持续深化药品医疗器械审评审批制度改革，持续推进疫情防控药械产品研发上市和质量监管，持续开展药品监管科学研究，持续加强药品监管体系和监管能力建设，药品监管改革创新踏上了新征程，开创了新局面。期待亚洲各国监管机构进一步深化交流与合作，共同提高监管能力

in Asian countries, jointly enhancing regulatory capacity and level, and making new contributions to global health.

Persons in charge of the Department of Science, Technology and International Cooperation, Department of Drug Registration, Department of Drug Regulation, Center for Drug Evaluation, and Center for Food and Drug Inspection participated in the meeting.

(April 6, 2022)

和水平，为全球健康事业发展做出新贡献。

科技国合司、药品注册司、药品监管司、药审中心、核查中心有关负责同志参加会议。 (2022-04-06)

Medical Devices

NMPA Announcement on Issuing Six Registration Technical Review Guidelines on Products such as Disposable High Pressure Contrast Syringes and Accessories

In order to strengthen the supervision and guidance on the registration of medical devices and further improve the quality of registration review, the National Medical Products Administration formulated the *Guidance for the Registration Review of Disposable High Pressure Contrast Syringes and Accessories*, *Guidance for the Registration Review of Internal Fixation System Products of Metal Plates (2021 Revision)*, *Guidance for Registration Review of Magnesium Orthopaedic Implants*, *Guidance for the Registration Review of Microcatheters*, *Guidance for the Registration Review of Disposable Endoscopic Injection Needles*, and *Guidance for the Registration Review of Intraocular Lens*, which were issued on January 11, 2022.

(January 17, 2022)

医疗器械

国家药监局关于发布一次性使用高压造影注射器及附件产品等6项注册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《一次性使用高压造影注射器及附件产品注册审查指导原则》《金属接骨板内固定系统产品注册审查指导原则（2021年修订）》《可降解镁金属骨科植入物注册审查指导原则》《微导管注册审查指导原则》《一次性使用内窥镜注射针注册审查指导原则》《人工晶状体注册审查指导原则》，于2022年1月11日发布。 (2022-01-17)

NMPA Notice on Issuing the Guidance for Compiling the Product Technical Requirements for Medical Devices

In order to improve the normalization and scientificity of technical evaluation of medical devices and guide medical device registrants/filing entities to prepare product technical requirements, in accordance with the *Regulations on Supervision and Administration of Medical Devices*, *Provisions for Medical Device Registration and Filing* and *Provisions for Registration and Filing of In-vitro Diagnostic Reagents*, the National Medical Products Administration has organized the revision of the *Guidance for Compiling the Product Technical Requirements for Medical Devices*, which was issued on February 8, 2022. (February 9, 2022)

国家药监局关于发布医疗器械产品技术要求编写指导原则的通告

为提高医疗器械技术审评的规范性和科学性，指导医疗器械注册人/备案人编写产品技术要求，根据《医疗器械监督管理条例》及《医疗器械注册与备案管理办法》《体外诊断试剂注册与备案管理办法》的规定，国家药品监督管理局组织修订了《医疗器械产品技术要求编写指导原则》，于2022年2月8日发布。 (2022-02-09)

NMPA Announcement on Issuing the Guidance for the Preparation of Annual Self-inspection Report of Medical Device Quality Management System

In order to strengthen the supervision over medical device manufacturing and guarantee the safety and effectiveness of medical devices, according to Paragraph 2 of Article 35 in the *Regulations on Supervision and Administration of Medical Devices*, the National Medical Products Administration organized to revise the *Guidance for the Preparation of Annual Self-Inspection Report of Medical Device Quality Management System*, which are hereby issued, and should take effect on May 1, 2022. The *Announcement on Issuing the Guidance for the Preparation of Annual Self-inspection Report for Quality Management System of Medical Device Manufacturers* issued by former China Food and Drug Administration on April 20, 2016 ([2016] No.76) shall be abolished at the same time. (March 24, 2022)

国家药监局关于发布医疗器械质量管理体系年度自查报告编写指南的通告

为加强医疗器械生产监管，保障医疗器械安全有效，根据《医疗器械监督管理条例》第三十五条第二款规定，国家药品监督管理局组织修订了《医疗器械质量管理体系年度自查报告编写指南》，现予发布，自2022年5月1日起施行。原国家食品药品监督管理总局《关于发布医疗器械生产企业质量管理体系年度自查报告编写指南的通告》（2016年第76号）同时废止。 (2022-03-24)

NMPA Announcement on Issuing the Guidance for Preparation of Contract Production Quality Agreement of Medical Devices

In order to strengthen the supervision over medical device production, guarantee the safety and effectiveness of medical devices, and guide registrants, filing entities and contract manufacturers of medical devices to jointly manage the quality of contract manufacturing of medical devices, according to Paragraph 2 of Article 34 in the *Regulations on Supervision and Administration of Medical Devices*, the National Medical Products Administration organized to revise the *Guidance for Preparation of Contract Manufacturing Quality Agreement of Medical Devices*, which was issued on March 22, 2022. (March 24, 2022)

国家药监局关于发布医疗器械委托生产质量协议编制指南的通告

为加强医疗器械生产监管，保障医疗器械安全有效，指导医疗器械注册人、备案人与受托生产企业共同做好医疗器械委托生产质量管理工作，根据《医疗器械监督管理条例》第三十四条第二款规定，国家药品监督管理局组织制定了《医疗器械委托生产质量协议编制指南》，于2022年3月22日发布。（2022-03-24）

NMPA Announcement on Issuing the List of Medical Devices Prohibited from Contract Manufacturing

In order to strengthen the supervision over medical device manufacturing and guarantee the safety and effectiveness of medical devices, according to the *Regulations on Supervision and Administration of Medical Devices* (State Council Order No.739), the National Medical Products Administration organized to revise the *List of Medical Devices Prohibited from Contract Manufacturing*, which was issued on March 11, 2022 and will take effect on May 1, 2022. The *Announcement on Issuing the List of Medical Devices Prohibited from Contract Manufacturing* issued by former CFDA (No.18 in 2014) should be abolished at the same time. (March 24, 2022)

国家药监局关于发布禁止委托生产医疗器械目录的通告

为加强医疗器械生产监管，保障医疗器械安全、有效，根据《医疗器械监督管理条例》（国务院令第739号），国家药品监督管理局组织修订了《禁止委托生产医疗器械目录》，于2022年3月11日发布，自2022年5月1日起施行，原国家食品药品监督管理总局《关于发布禁止委托生产医疗器械目录的通告》（2014年第18号）同时废止。（2022-03-24）

Cosmetics

NMPA Announcement on Issuing the Provisions for the Administration of Adverse Reaction Monitoring of Cosmetics

In order to regulate the ADR monitoring for cosmetics, according to the *Regulations on Supervision and Administration of Cosmetics and the Provisions for Supervision and Administration of Cosmetic Manufacturing and Distribution*, the NMPA formulated the *Provisions for the Administration of Adverse Reaction Monitoring of Cosmetics*, which was issued on February 15, 2022 and will come into force on October 1, 2022. (February 15, 2022)

化妆品

国家药监局关于发布《化妆品不良反应监测管理办法》的公告

为规范化妆品不良反应监测工作，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《化妆品不良反应监测管理办法》，于2022年2月15日公布，自2022年10月1日起施行。（2022-02-15）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.

• 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。如有出入，以中文为准。

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