NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

NMPA Held the Work Conference on Promoting Foreign Trade and Foreign Investment

On November 15, 2022, in order to thoroughly implement the decisions and plans of the CPC Central Committee and the State Council, and focus on the new missions and requirements proposed in the Report to the 20th National Congress of the Communist Party of China, the National Medical Products Administration (NMPA) held the Work Conference on Promoting Foreign Trade and Foreign Investment to study and deploy how to further strengthen the services for foreign-invested pharmaceutical enterprises and how to well guarantee the services for major foreign investment projects. Zhao Junning, Party member and Deputy Commissioner of NMPA, attended and addressed at the conference.

Zhao Junning said that NMPA attaches great importance to the services for foreign trade and foreign investment, and has issued the *Notice of Comprehensive Department of NMPA on Further Strengthening the Services for Foreign-invested Enterprises* and the *Notice of Comprehensive Department of NMPA on Establishing a Leading Group for Coordinating Foreign Trade and Foreign Investment*, making a comprehensive deployment of services for promoting foreign trade and foreign investment. Based on the guidance of the 20th National Congress of the CPC, NMPA will make every effort to promote the services for foreign trade and foreign investment in accordance with relevant general requirements.

Zhao Junning stressed that all localities and departments should further strengthen the services for foreign trade and foreign investment, and on the basis of approval and supervision over drugs and medical devices for COVID-19 prevention, accelerate the review and approval of drugs and medical devices, strengthen quality supervision over the products for COVID-19 prevention, and solidly promote major foreign investment projects to go into operation. First, continue to promote all work to be implemented with effective outcome in accordance with the requirements of the Notice on strengthening the services for foreign-invested enterprises. Second, deeply understand the appeals of foreign chambers of commerce and associations and foreign-invested enterprises by fullly use existing communication channels and mechanisms. Third, provincial administrations should guarantee the services for major foreign investment projects in accordance with principles at the localities under the guidance of NMPA.

Focusing on the local promotion of foreign trade and foreign investment and the progress in promoting major foreign investment projects, the provincial administrations participating in the conference deeply exchanged experiences and good practices, and make clear their future work goals and measures.

The officials in charge of relevant NMPA departments and directly affiliated institutions related to drugs, medical devices and cosmetics attended the conference on site. The officials in charge of 11 provincial medical products administrations of Tianjin, Hebei, Jilin, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Henan, Hubei and Guangdong involved in major foreign investment projects attended the conference via video.

(November 15, 2022)

国家药监局召开推进外贸外资工作会议

2022年11月15日，为深入贯彻落实党中央、国务院决策部署，聚焦党的二十大报告提出的新使命新要求，国家药监局召开推进外贸外资工作会议，研究部署进一步加强医药外资企业服务，做好重点外资项目服务保障工作举措。国家药监局党组成员、副局长赵军宁出席会议并发表讲话。

赵军宁表示，国家药监局高度重视服务外贸外资工作，先后印发《国家药监局综合司关于进一步加强外资企业服务工作的通知》和《国家药监局综合司关于成立外贸外资协调工作领导小组的通知》，对推进外贸外资服务工作作出全面部署。国家药监局将以党的二十大精神为指引，按照外贸外资服务工作总体要求，全力以赴推进外贸外资服务工作。

赵军宁强调，各地及各部门要进一步加大服务外贸外资工作力度，在做好防疫药品和医疗器械审批监管的基础上，加快药品和医疗器械审评审批，加强对抗疫产品的质量监管，扎实推动医药重点外资项目落地投产。一是切实按照加强外资企业服务工作有关通知要求，持续推进各项工作落地见效。二是充分利用现有的沟通渠道和机制，深入了解在华外国商协会、外资企业的问题诉求。三是按照属地原则，由国家局指导省局，做好对重点外资项目的服务保障工作。

各参会省局围绕本地区推进外贸外资工作、推动重点外资项目进展等方面，深入交流好的经验做法，明确未来工作目标和举措。

国家药监局药品、医疗器械和化妆品各相关司局和直属单位有关负责同志现场参会，重点外资项目涉及的天津、河北、吉林、上海、江苏、浙江、福建、山东、河南、湖北和广东等11个省局有关负责同志通过视频在线参会。

（2022-11-15）

Published by
China Center for Food and Drug International Exchange

Drugs

Sanhan Huashi Granules Approved for Marketing

The National Medical Products Administration (NMPA) recently approved Sanhan Huashi Granules for marketing, a category 3.2 compound preparation of traditional Chinese medicine (TCM) originated from classic recipes. This medicine is used for epidemic diseases caused by cold-dampness stagnating in the lung pattern. The drug marketing authorization holder is Jiangsu Kanion Pharmaceutical Co., Ltd.

The marketing of this medicine provides another therapeutic option for the treatment of epidemic diseases.

(October 9, 2022)

NMPA Announcement on putting into use the electronic certificates of Documentation for Export of APIs to EU and Certificate of a Pharmaceutical Product

As part of the efforts to implement the major decisions and plans of the Communist Party of China Central Committee and the State Council on deepening the reforms to separate operating permits from business licenses, in order to further improve the business environment, stimulate the vitality of market entities, optimize the service capacity for "internet + drug supervision" of the National Medical Products Administration (NMPA), and provide drug export enterprises with more efficient and convenient administrative services, it is decided that the electronic certificates of the *Documentation for Export of APIs to EU* and *Certificate of a Pharmaceutical Product* will be officially put into use from Dec 1, 2022. Relevant matters are hereby announced as follows.

I. From Dec 1, 2022, the electronic certificates of the *Documentation for Export of APIs to EU* and *Certificate of a Pharmaceutical Product* will be put into use. The electronic certificate and the paper version are equally authentic.

II. A new template for the *Certificate of a Pharmaceutical Product* (see annex) will be put into use in line with China's pharmaceutical export practices and the latest World Health Organization guidelines. From Dec 1, 2022, all provincial-level drug regulatory authorities shall issue the *Certificate of a Pharmaceutical Product* in accordance with the new template.

III. Efforts should be made to promote and guide the use of electronic certificates. To use the electronic certificate produced and issued by the application system of the NMPA, the applicant shall first register and be authenticated with real-name in the Online Office Hall of the NMPA. Enter the "My Certificates" (Chinese name in Pinyin: Wodezhengzhao) section in the legal representative space in the Online Office Hall, or log into the NMPA APP (Chinese name in Pinyin: Zhongguoyaojian) to view and download the corresponding electronic certificate. The applicant shall properly keep the electronic certificate. Frequently asked questions and answers related to electronic certificates produced and issued by the NMPA can be found in the column of "Help for Matters Related to Electronic Certificate" in the Online Office Hall of the NMPA.

IV. Where electronic certificates produced and issued by the provincial application system are used, the provincial drug regulatory department shall clarify the relevant guidelines to enterprises within its administrative region and provide guidance and services.

(October 31, 2022)

药品

国家药监局批准散寒化湿颗粒上市

近日，国家药品监督管理局批准3.2类中药新药散寒化湿颗粒上市。该药品用于寒湿郁肺所致疫病。药品上市许可持有人为江苏康缘药业股份有限公司。

该品种上市为疫病的治疗提供了又一种治疗选择。

（2022-10-09）

国家药监局关于启用《出口欧盟原料药证明文件》和《药品出口销售证明》电子证明的公告

为深入贯彻落实党中央、国务院关于深化“证照分离”改革重大决策部署，优化营商环境，进一步激发市场主体发展活力，提升国家药监局“互联网+药品监管”应用服务水平，为药品出口企业提供更加高效便捷的政务服务，经研究决定，自2022年12月1日起，正式启用《出口欧盟原料药证明文件》和《药品出口销售证明》电子证明，现将有关事项公告如下：

一、 自2022年12月1日起，对签发的《出口欧盟原料药证明文件》和《药品出口销售证明》启用电子证明。电子证明与纸质证明具有同等效力。

二、 结合我国药品出口工作实践和世卫组织相关最新指南，启用《药品出口销售证明》新模板。自2022年12月1日起，各省级药品监管部门应当按照更新后的模板签发《药品出口销售证明》。

三、 做好启用电子证明的宣贯和指导工作。使用国家药监局应用系统制发的电子证明的，申请人须先行在国家药监局网上办事大厅注册并实名认证，进入网上办事大厅法人空间“我的证照”栏目，也可登录“中国药监APP”，查看下载相应的电子证明。申请人应妥善保管电子证明。国家药监局制发的电子证明常见问题及解答，见国家药监局网上办事大厅电子证照帮助栏目。

四、 使用本省应用系统制发的电子证明的，省级药品监管部门应当向行政区域内企业明确有关办事指南，做好指导和服务。

（2022-10-31）

Toludesvenlafaxine Hydrochloride Sustained-Release Tablets Approved for Marketing

Recently, the Class I innovative chemical drug Toludesvenlafaxine Hydrochloride Sustained-Release Tablets (Chinese trade name: 若欣林®) of Luye Pharma Group is approved for marketing by China NMPA. This drug is an innovative drug with independent intellectual property rights, of which the research and development is taken independently in China. It is indicated for the treatment of major depressive disorder.

The antidepressant effect of Toludesvenlafaxine Hydrochloride may be related to the enhancement of serotonin (5-HT) and norepinephrine (NE) effects in the central nervous system by inhibiting the reuptake of 5-HT and NE. This drug provides more treatment options available for patients with major depressive disorder.

(November 3, 2022)

国家药监局批准盐酸托鲁地文拉法辛缓释片上市

近日，国家药品监督管理局批准山东绿叶制药有限公司申报的1类创新药盐酸托鲁地文拉法辛缓释片（商品名：若欣林）上市。该药为我国自主研发并拥有自主知识产权的创新药，适用于抑郁症的治疗。

盐酸托鲁地文拉法辛的抗抑郁作用可能与通过抑制5-羟色胺（5-HT）、去甲肾上腺素（NE）的再摄取而增强中枢神经系统的5-HT、NE效应有关。该药品的上市为抑郁症患者提供了更多的治疗选择。

（2022-11-03）

Linperlisib Tablet Approved with Condition for Marketing

Recently, linperlisib tablet (Chinese trade name: 因他瑞®) of Yingli Pharma has been approved with condition for marketing through the priority review and approval procedure by NMPA in China. This product is an innovative drug with independent intellectual property rights, of which the research and development is taken independently in China. Linperlisib tablet is approved for the treatment of relapsed/refractory follicular lymphoma adult patients who have received two or more prior systemic therapies.

Linperlisib is a phosphoinositide 3-kinase delta (PI3Kδ) selective inhibitor. It is able to reduce the level of phosphorylated AKT protein by inhibiting PI3Kδ protein, thereby inducing apoptosis and inhibiting the proliferation of malignant B cells and primary tumor cells. The marketing of this product provides a treatment option for relapsed/refractory follicular lymphoma adult patients who have no other existing treatment options.

(November 9, 2022)

国家药监局附条件批准林普利塞片上市

近日，国家药品监督管理局通过优先审评审批程序附条件批准上海璎黎药业有限公司申报的1类创新药林普利塞片（商品名：因他瑞）上市。该药为我国自主研发并拥有自主知识产权的创新药，适用于既往接受过至少两种系统性治疗的复发或难治滤泡性淋巴瘤成人患者。

林普利塞为磷脂酰肌醇-3-激酶的δ亚型（PI3Kδ）选择性抑制剂。林普利塞片可抑制PI3Kδ蛋白的表达，降低AKT蛋白磷酸化水平，从而诱导细胞凋亡以及抑制恶性B细胞和原发肿瘤细胞的增殖。该药品的上市为经现有治疗手段治疗后复发难治的滤泡淋巴瘤成人患者提供了治疗选择。

（2022-11-09）

Medical devices

Software for surgical planning of intracranial aneurysms approved for marketing

Recently, the innovative product “software for surgical planning of intracranial aneurysms (Uknow®)” of UnionStrong Technology (Beijing) Inc. is approved for marketing by China NMPA.

The product is composed of the application

医疗器械

颅内动脉瘤手术计划软件获批上市

近日，国家药品监督管理局经审查，批准了强联智创（北京）科技有限公司生产的“颅内动脉瘤手术计划软件”创新产品注册

program and authorization files. The software function module includes data loading, display interaction, data management, data processing and log. The product is applied for the display, segmentation, measurement and processing of three-dimensional tomographic images of X-ray angiography for patients with cerebrovascular diseases. It assists doctors in planning the path and shape of the microcatheter used for aneurysm coil embolization during neurointerventional surgery.

This product uses medical image processing technology to process the three-dimensional tomography image of X-ray angiography for patients with intracranial aneurysms, to realize three-dimensional vascular reconstruction, aneurysm segmentation and automatic measurement, and to assist in planning the path of the microcatheter and the shape of shaping needle, so as to help doctors with the preoperative planning. Compared with the traditional method of neurointerventional surgery, this product can improve the one-time correct anatomic placement rate and shorten the delivery time of the microcatheter, decrease the incidence of complications caused by the repeated vascular stimulation of microcatheter during operation, and reduce the X-ray radiation time to doctors and patients.

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

(October 11, 2022)

Flow-guided tight-mesh stent approved for marketing

Recently, the innovative product "flow-guided tight-mesh stent" produced by AccuMedical Beijing LTD is approved by China NMPA.

The implant of flow-guided tight-mesh stent is a cylindrical self-expanding stent made of self-expanding cobalt-chromium alloy and platinum-tungsten alloy wire. The delivery system is composed of push rod, stainless steel coil, funnel, support pad, braided tube, marking ring, platinum coil, warning mark, heat shrinkable tube and adhesive. The innovation of this product is to use the mechanical balloon in the delivery system to actively assist the expansion from the stent inside, push the stent to the treatment site, and realize the recovery of the stent when needed.

This product is used for adult patients with unruptured cystic or fusiform wide-necked aneurysms (neck width ≥ 4mm or dome-to-neck ratio <2) of the internal carotid artery (petrosal bone segment to terminal) and vertebral artery, and the diameter of the vessel carrying aneurysms is ≥2.0mm and ≤5.6mm. The marketing of this product brings new options to patients.

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

(October 26, 2022)

申请。

该产品由应用程序和授权文件组成，软件功能模块包括数据加载、显示交互、数据管理、数据处理和日志。产品用于脑血管病患者X射线血管造影三维体层图像的显示、分割、测量和处理，辅助医生在神经介入手术时进行动脉瘤弹簧圈栓塞用的微导管路径和塑形规划。

该产品利用医学图像处理技术对颅内动脉瘤患者的X射线血管造影三维体层图像进行处理，实现三维血管重建、动脉瘤分割和自动测量及微导管路径和塑形针形状规划，帮助医生进行术前方案规划。与传统神经介入手术方式相比，该产品可以提升微导管一次性到位率，缩短微导管输送时间，降低术中微导管反复推送对血管刺激导致的并发症发生概率，减少医生、患者X射线辐射时间。

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。

（2022-10-11）

血流导向密网支架获批上市

近日，国家药品监督管理局经审查，批准了艾柯医疗器械（北京）股份有限公司生产的创新产品“血流导向密网支架”注册。

血流导向密网支架的植入物为柱形自扩张支架，由自膨胀式钴铬合金和铂钨合金丝编织而成。输送系统由推送杆、不锈钢线圈、漏斗、支撑垫、编织管、标记环、铂金线圈、警告标记、热缩管、粘接剂组成。该产品的创新点在于利用输送系统中的机械球囊，从支架内部进行主动辅助膨胀，将支架推送到治疗部位，并且在需要时实现对支架的回收。

该产品用于成人患者颈内动脉（岩骨段至末端）与椎动脉未破裂的囊状或梭状的宽颈（瘤颈宽≥4mm或瘤体/瘤颈比<2）动脉瘤，且载瘤血管直径≥2.0mm且≤5.6mm。产品的上市将为患者带来新的治疗选择。

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。

（2022-10-26）

Aspheric diffractive multifocal intraocular lens approved for marketing

Recently, the innovative product "aspheric diffractive multifocal intraocular lens" produced by Eyebright Medical Technology (Beijing) Inc. is approved for marketing.

The aspheric diffractive multifocal intraocular lens is a one-piece/posterior chamber intraocular lens, which is a foldable modified L loop. The main part and supporting part of the product are made of the copolymer of ethyl acrylate and ethyl methacrylate, added with ultraviolet absorber, and the surface is modified with heparin. The innovation of this product is that its optical part adopts the design of combining diffraction-splitting and non-spherical surface, which enables multi focus through the diffraction technology, and therefore it becomes the first in China.

This product is used for vision correction of adult cataract patients. It is expected to provide far and near focus, which to some extent makes up for the poor vision of single focus intraocular lens. The marketing of this product brings new treatment options to patients.

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

(October 31, 2022)

非球面衍射型多焦人工晶状体获批上市

近日，国家药品监督管理局经审查，批准了爱博诺德（北京）医疗科技股份有限公司生产的创新产品“非球面衍射型多焦人工晶状体”注册。

非球面衍射型多焦人工晶状体为一件式/后房人工晶状体，可折叠，襻形为改良L型。该产品主体及支撑部分均由丙烯酸乙酯、甲基丙烯酸乙酯共聚物材料制成，添加了紫外线吸收剂，表面经肝素改性。该产品的创新点在于其光学部采用衍射分光和非球面相结合的设计，衍射技术是实现多焦点的核心，在国内属于首创。

该产品用于成年白内障患者的视力矫正，预期可提供远、近两个焦点，一定程度上弥补了单焦点人工晶状体视力不佳的不足。产品的上市将为患者带来新的治疗选择。

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。

（2022-10-31）

Left Atrial Appendage Occluder System Approved for Marketing

Recently, the innovative product "left atrial appendage occluder system" of Hangzhou Deno Electrophysiology Medical Technology Inc. is approved for marketing by China NMPA.

The left atrial appendage occluder system consists of a left atrial appendage occluder and a delivery device, in which the left atrial appendage occluder is connected by a sealed disc and an anchoring disc. The delivery device is composed of a delivery sheath, a dilator, a loader, a delivery cable and a hemostasis valve. The design of the sealed disc and the anchoring disc of the product adopts an innovative patented design, which makes full use of the self-expanding of the NiTi wire braid structure, and can meet the clinical needs of different forms of left atrial appendage occlusion to a certain extent.

This product is indicated for patients with nonvalvular atrial fibrillation who are at risk for stroke (CHA2DS2-VASc score ≥2) and who are contraindicated to long-term oral anticoagulation. The marketing of the product is expected to benefit more patients.

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

(November 10, 2022)

左心耳封堵器系统获批上市

近日，国家药品监督管理局经审查，批准了杭州德诺电生理医疗科技有限公司生产的创新产品“左心耳封堵器系统”注册。

左心耳封堵器系统由左心耳封堵器和输送器组成，其中左心耳封堵器由密封盘和锚定盘连接而成。输送器由输送鞘管、扩张器、装载器、输送钢缆和止血阀组成。该产品的密封盘和锚定盘的设计均采用了创新的专利设计，充分利用了镍钛丝编织结构的自适应性，一定程度上可满足临床对不同形态左心耳的封堵需求。

该产品适用于有卒中风险（CHA2DS2-VASc评分≥2分）且长期口服抗凝治疗禁忌的非瓣膜性房颤患者。产品的上市预期让更多的患者受益。

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。

（2022-11-10）

NMPA Announcement on the Management Category of Medical Sodium Hyaluronate Products (2022 No.103)

In order to strengthen the supervision and management of medical sodium hyaluronate products, further standardize the registration (filing) of relevant products and ensure the safety and effectiveness of medical devices for public use, in accordance with the relevant provisions of the *Drug Administration Law* and the *Regulations for Supervision and Administration of Medical Devices*, relevant matters on the management of such products are hereby announced as follows:

I. According to different intended uses (indications), working principles, etc., medical sodium hyaluronate products shall be managed separately under the following circumstances:

(I) Products used for the treatment of arthritis, dry eye, etc., shall be managed as drugs.

(II) Where any drug component conforms to the following circumstances and does not contain any drug component exerting pharmacological, metabolic or immunological effects, it shall be managed as a medical device, and of which the management category shall not be lower than Class II.

1. When it is used for contact lens care products, the products shall be managed as Class III medical devices.

2. When it is used as absorbable surgical anti-adhesion materials, the products shall be managed as Class III medical devices.

3. When it is used as ophthalmic viscoelastic, the products shall be managed as Class III medical devices.

4. When it is used as injection filling to increase tissue volume, the products shall be managed as Class III medical devices.

5. When the products are injected into dermis layer to improve skin conditions mainly through the moisturizing and hydrating effects of sodium hyaluronate contained, they shall be managed as Class III medical devices.

6. When the products are used for repairing the application of glucosamine protective layer in bladder epithelium, they shall be managed as Class III medical devices.

7. When the products are used as medical dressing, if the products can be partially or completely absorbed by the human body, or used for chronic wounds, they shall be managed as Class III medical devices; if the products cannot be absorbed by the human body and used for non-chronic wounds, they shall be managed as Class II medical devices.

8. When it is used as auxiliary dressing for improving pathological skin scars and assisting in preventing pathological skin scars, the products shall be managed as Class II medical devices.

9. When it is used as auxiliary materials for oral ulcer and oral tissue wound healing treatment, the products shall be managed as Class II medical devices.

10. When it is used as lubricants for introducing body cavity devices (excluding condoms), the products shall be managed as Class II medical devices.

11. Condoms containing sodium hyaluronate lubricants shall be managed as Class II medical devices.

(III) For drug-device combination products containing sodium hyaluronate, it shall be determined as a drug-led or device-led combination product according to the primary mode of action of the product. The addition of antimicrobial ingredients to drug-device combination products is not

国家药监局关于医用透明质酸钠产品管理类别的公告（2022年第103号）

为加强医用透明质酸钠（玻璃酸钠）产品的监督管理，进一步规范相关产品注册（备案），保证公众用药用械安全有效，根据《药品管理法》《医疗器械监督管理条例》相关规定，现就该类产品管理有关事宜公告如下：

一、根据不同预期用途（适应症）、工作原理等，医用透明质酸钠（玻璃酸钠）产品按照以下情形分别管理：

（一）用于治疗关节炎、干眼症等的产品，按照药品管理。

（二）符合以下情形，且不含发挥药理学、代谢学或免疫学作用的药物成分时，按照医疗器械管理，其管理类别不得低于第二类。

1.作为接触镜护理产品应用时，按照第三类医疗器械管理。

2.作为可吸收外科防粘连材料应用时，按照第三类医疗器械管理。

3.作为眼用粘弹剂应用时，按照第三类医疗器械管理。

4.作为注射填充增加组织容积产品应用时，按照第三类医疗器械管理。

5.作为注射到真皮层，主要通过所含透明质酸钠的保湿、补水等作用，改善皮肤状态应用时，按照第三类医疗器械管理。

6.用于修复膀胱上皮氨基葡萄糖保护层应用时，按照第三类医疗器械管理。

7.作为医用敷料应用时，若产品可部分或者全部被人体吸收，或者用于慢性创面，按照第三类医疗器械管理；若产品不可被人体吸收且用于非慢性创面，按照第二类医疗器械管理。

8. 作为辅助改善皮肤病理性疤痕，辅助预防皮肤病理性疤痕形成的疤痕修复敷料应用时，按照第二类医疗器械管理。

9.作为口腔溃疡、口腔组织创面愈合治疗辅助材料应用时，按照第二类医疗器械管理。

10.作为体腔器械（不含避孕套）导入润滑剂应用时，按照第二类医疗器械管理。

11.含有透明质酸钠润滑剂的避孕套，按照第二类医疗器械管理。

（三）对于含有透明质酸钠（玻璃酸钠）的药械组合产品，应当根据产品首要作用方式判定为以药品作用为主或者以医疗器械作用为主的药械组合产品。不提倡药械组

advocated.

Medical dressing products containing antimicrobial ingredients and injection fillers for plastic surgery containing drugs shall be determined according to the following principles:

1. For medical dressing products containing antibacterial ingredients, non-clinical pharmacodynamic studies and/or clinical studies shall be provided to determine whether the products have antibacterial therapeutic effect. For the non-clinical pharmacodynamic study and/or clinical study and evaluation criteria used to determine whether the products have antibacterial therapeutic effect, refer to the non-clinical and clinical technical guidelines related to drug research and development. (1) If non-clinical pharmacodynamic studies and/or clinical studies confirm that the products have a clear antibacterial therapeutic effect, among which, the products achieving the intended use mainly through antibacterial therapeutic effect, are determined as drug-led combination products; the products achieving the intended use mainly through physical coverage of wound surface and absorption of exudate, are determined as device-led combination products. (2) If non-clinical pharmacodynamic studies and/or clinical studies do not show that the products have antibacterial therapeutic effects, they shall be managed as medical devices.

2. Injection fillers for plastic surgery containing drugs for local anesthetics (such as lidocaine hydrochloride, amino acids, vitamins) to increase tissue volume, are determined as device-led combination products.

3. Injecting materials for medical cosmetology containing drugs for local anesthetics (such as lidocaine hydrochloride, amino acids, vitamins, etc.) to improve skin conditions mainly through the moisturizing and hydrating effects of sodium hyaluronate contained, are determined as device-led combination products.

4. Products as lubricants for introducing body cavity devices (excluding condoms) are determined as device-led combination products.

II. Products applied to the skin, hair, nails, lips and other human surfaces by rubbing, spraying or other similar methods for the purpose of cleaning, protecting, modifying and beautification shall not be managed as drugs or medical devices.

Products used to relieve vaginal dryness (excluding those used for vaginal wound care) shall not be managed as drugs or medical devices.

The lotions, disinfectants, pads etc. containing disinfectant which are only used for disinfection of damaged skin and wound surface shall not be managed as drugs or medical devices.

III. Where the modified sodium hyaluronate is verified to be consistent with sodium hyaluronate in terms of relevant physical, chemical and biological properties, the management attributes and management categories may be implemented by referring to this *Announcement*.

IV. From the date of issuance of the *Announcement*, the registration application of medical sodium hyaluronate products shall be accepted in accordance with the aforesaid management categories.

V. For the varieties under review and approval that have been accepted as registration applications for drugs or medical devices, the review and approval shall continue to be conducted as drugs or medical devices, and if the requirements are met, the drug approval number or medical device registration certificate shall be issued. Where it is necessary to change the management attributes or categories, the validity period of its approval number

合产品添加抗菌成分。

对含有抗菌成分的医用敷料产品、含有药物的整形用注射填充物等按下述原则判定：

1.含有抗菌成分的医用敷料产品，应当提供非临床药效学研究和/或临床研究证实产品是否具有抗菌治疗作用。用于判定产品是否具有抗菌治疗作用的非临床药效学研究和/或临床研究及评判标准可参考药品研发相关的非临床和临床技术指导原则。（1）如果非临床药效学研究和/或临床研究证实产品具有明确的抗菌治疗作用，其中，主要通过抗菌治疗作用实现其预期用途的产品判定为以药品为主的药械组合产品；主要通过创面物理覆盖、渗液吸收等作用实现其预期用途的产品判定为以医疗器械为主的药械组合产品。（2）如果非临床药效学研究和/或临床研究未显示产品具有抗菌治疗作用，则产品按照医疗器械管理。

2.含有局麻药等药物（如盐酸利多卡因、氨基酸、维生素）、主要通过填充增加组织容积的整形用注射填充物，判定为以医疗器械为主的药械组合产品。

3.含有局麻药等药物（如盐酸利多卡因、氨基酸、维生素等）、主要通过所含透明质酸钠的保湿、补水等作用，改善皮肤状态的医疗美容用注射材料，判定为以医疗器械为主的药械组合产品。

4.含有药物的体腔器械（不含避孕套）导入润滑剂，判定为以医疗器械为主的药械组合产品。

二、以涂擦、喷洒或者其他类似方法，施用于皮肤、毛发、指甲、口唇等人体表面，以清洁、保护、修饰、美化为目的的产品，不按照药品或者医疗器械管理。

用于缓解阴道干燥的产品（不包括用于阴道创面护理的产品），不按照药品或者医疗器械管理。

仅用于破损皮肤、创面消毒的含消毒剂成分的洗液、消毒液、消毒棉片等，不按照药品或者医疗器械管理。

三、经修饰的透明质酸钠（玻璃酸钠）经验证后如相关物理、化学、生物特性与透明质酸钠一致，管理属性和管理类别可参照本公告执行。

四、自公告发布之日起，按照上述管理类别受理医用透明质酸钠（玻璃酸钠）产品的注册申请。

五、已经按照药品或医疗器械受理的注册申请，正在审评、审批的品种，继续按照药品或医疗器械进行审评、审批，符合要求的，核发药品批准文号或医疗器械注册证

or registration certificate shall be limited to December 31, 2024.

VI. Where it is necessary to change the management attributes and management categories of a product that has obtained a drug approval number or a medical device registration certificate, the original drug approval number or medical device registration certificate shall continue to be valid within the validity period of the certificate; and the enterprise involved shall actively carry out the conversion work in accordance with the relevant requirements of the corresponding management attributes and categories, and complete the conversion before December 31, 2024. Where the original drug approval number or medical device registration certificate expires during the conversion work, under the premise that the product is safe and effective and no serious adverse event or quality accident occurs after marketing, the enterprise may file an extension application to the original review and approval authority according to the original management attributes and categories, and extend the validity period of the original drug approval number or medical device registration certificate shall not exceed December 31, 2024.

VII. Cold compress gel, photon gel, liquid dressing, paste dressing and other products that have been filed as Class I medical devices shall be governed by the relevant requirements of the *Announcement on Implementing the Catalogue of Class I Medical Devices* (NMPA Announcement 2021 No. 107) and the *Announcement on Adjusting Some Contents of the Catalogue of Medical Devices* (NMPA Announcement 2022 No. 25).

VIII. All relevant enterprises shall earnestly implement the main body responsibility for product quality and safety to ensure the safety and effectiveness of the marketed products. Drug regulatory departments at all levels shall strengthen publicity and implementation training and earnestly carry out review and approval and post-marketing surveillance on relevant products.

IX. This *Announcement* shall come into force on the date of issuance, and the *Announcement on the Management Categories of Medical Sodium Hyaluronate Products* (former CFDA Announcement 2009 No. 81) shall be abolished simultaneously.

(November 14, 2022)

书。其中，需要改变管理属性或类别的，限定其批准文号或注册证书的有效期截止日期为2024年12月31日。

六、已获得药品批准文号或医疗器械注册证的产品，需要改变管理属性、管理类别的，原药品批准文号或医疗器械注册证在证书有效期内继续有效；所涉及企业应当按照相应管理属性和类别的有关要求积极开展转换工作，在2024年12月31日之前完成转换。开展转换工作期间原药品批准文号或医疗器械注册证到期的，在产品安全有效且上市后未发生严重不良事件或质量事故的前提下，企业可按原管理属性和类别向原审批部门提出延期申请，予以延期的，原药品批准文号或医疗器械注册证有效期不得超过2024年12月31日。

七、已按第一类医疗器械备案的冷敷凝胶、光子冷凝胶、液体敷料、膏状敷料等产品，按照《关于实施〈第一类医疗器械产品目录〉有关事项的通告》（国家药监局通告2021年第107号）和《关于调整〈医疗器械分类目录〉部分内容的公告》（国家药监局公告2022年第25号）有关要求执行。

八、各相关企业应当切实落实产品质量安全主体责任，确保上市产品的安全有效。各级药品监督管理部门要加强宣贯培训，切实做好相关产品审评审批和上市后监管工作。

九、本公告自发布之日起实施，《关于医用透明质酸钠产品管理类别的公告》（原国家食品药品监督管理局公告2009年第81号）同时废止。

（2022-11-14）

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

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