NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

NMPA Announcement on Issuing the Rules for Vaccine Manufacturing and Distribution(2022 No.55)

In order to implement the requirements of the *Drug Administration Law of the People's Republic of China*, *Vaccine Administration Law of the People's Republic of China* and other laws and regulations, build a scientific and effective supervision and administration system for the manufacturing and distribution of vaccines, and standardize the manufacturing and distribution management activities of vaccines in accordance with the characteristics of vaccine products and vaccine regulatory requirements, NMPA organized to formulate the *Rules for Vaccine Manufacturing and Distribution*, which are issued on July 8, 2022 and shall come into force on the date of issuance.

(July 8, 2022)

国家药监局关于发布《疫苗生产流通管理规定》的公告（2022年 第55号）

为贯彻落实《中华人民共和国药品管理法》和《中华人民共和国疫苗管理法》等法律法规要求，构建科学、有效的疫苗生产流通监督管理体系，根据疫苗产品特性和疫苗监管要求，依法对疫苗的生产、流通管理活动进行规范，国家药监局组织制订了《疫苗生产流通管理规定》，于2022年7月8日发布并施行。

（2022-07-08）

SURGICEL Powder and SURGICEL Endoscopic Applicator Approved for Marketing

Recently, the SURGICEL Powder and SURGICEL Endoscopic Applicator, an innovative product of Ethicon, LLC, is approved for marketing by China NMPA.

This product consists of model 3013SP, namely oxidized regenerated cellulose absorbable hemostatic particles (pre-installed with device) and model 3123SPEA, namely oxidized regenerated cellulose absorbable hemostatic particles endoscopic application catheter device. Both are sterilized by radiation for single use. Model 3013SP is an applicator pre-loaded with 3g hemostatic particles made of compacted fine fibers through a patented process, which can be used for an open surgery; model 3123SPEA combined with 3013SP can be used for endoscopic surgery. This product is suitable for surgical or endoscopic surgery (except ophthalmology, neurosurgery, and urology), when ligation or other traditional control methods are not applicable or ineffective, as an auxiliary control of capillary, venule and arteriole bleeding. This product is the first granular oxidized regenerated cellulose hemostatic product. Its granules are made of compacted fine fibers with a patented process. And its matched powder applicator is used to make the instrument face the areas - without affecting the granules' effective and uniform spray, which is convenient for surgical or endoscopic applications.

The NMPA will strengthen the post-marketing surveillance on the product to protect the patient's safety in use of medical device.

(August 3, 2022)

可吸收再生氧化纤维素止血颗粒获批上市

近日，国家药品监督管理局经审查，批准了Ethicon,LLC生产的创新产品“可吸收再生氧化纤维素止血颗粒”注册。

该产品由型号3013SP即再生氧化纤维素可吸收止血颗粒（预装含装置）和型号3123SPEA 即再生氧化纤维素可吸收止血颗粒内窥镜施用导管装置组成。两者均经辐射灭菌，一次性使用。型号3013SP为预装3g经专利工艺压实细纤维制成的止血颗粒的施用装置，用于开放手术；型号3123SPEA，可配合3013SP用于内窥镜手术。

该产品适用于外科手术或内窥镜手术中（眼科、神经外科、泌尿外科除外），结扎法或其他传统控制方法不适用或无效时，作为辅助控制毛细血管、小静脉和小动脉出血。该产品为首个颗粒状的再生氧化纤维素止血产品，其颗粒由专利工艺压实细纤维制成，其配套用的施粉装置可以使器械朝向不影响颗粒的有效均匀喷射，便于外科手术或内窥镜手术中的应用。

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。

（2022-08-03）

Published by
China Center for Food and Drug International Exchange

FilmArray Meningitis/Encephalitis (ME) Panel (closed nested multiplex PCR and melting curve method) Approved for Marketing

Recently, the "FilmArray Meningitis/Encephalitis (ME) Panel (closed nested multiplex PCR melting curve method)", an innovative product by BioFire Diagnostics, LLC, is approved by China NMPA.

The product is composed of FilmArray ME test bar, sample buffer, dissolving solution, disposable red sample injection tube and independently packaged pipette. It is a disposable closed detection reagent for in vitro qualitative detection of nucleic acids of 14 bacteria, viruses and invisible cocci in cerebrospinal fluid (CSF) samples from patients with signs/symptoms of meningitis and/or encephalitis.

The product adopts closed nested multiplex PCR melting curve method, based on nested multiplex PCR amplification and melting curve analysis technology, that the samples broken by mechanical grinding are detected and analyzed. The closed nested multiplex PCR amplification and melting curve analysis technology improves the reaction sensitivity and specificity of the assay, and the system software automatically evaluates the data and reports the results.

This product can detect and identify 14 potential pathogens related to central nervous system infection in CSF, obtain the detection results within about 1 hour, accelerate the pathogen diagnosis of ME, so as to carry out targeted clinical treatment as early as possible and reduce the burden of ME-related diseases on patients.

The NMPA will strengthen the post-marketing surveillance on the product to protect patients' safety in use of medical device.

(August 5,2022)

脑炎/脑膜炎多重病原体核酸联合检测试剂盒(封闭巢式多重PCR熔解曲线法)获批上市

近日，国家药品监督管理局经审查，批准了拜奥法尔诊断有限责任公司（BioFire Diagnostics，LLC）生产的“脑炎/脑膜炎多重病原体核酸联合检测试剂盒(封闭巢式多重PCR熔解曲线法)”创新产品注册申请。

该产品由FilmArray ME测试条、样本缓冲液、溶解液、一次性使用红色样本注射管和独立包装移液管组成，是一种一次性封闭检测试剂，用于体外定性检测具有脑膜炎及/或脑炎体征及/或症状的人群的脑脊液(CSF)样本中的14 种细菌、病毒和隐形球菌的核酸。

该产品采用封闭巢式多重PCR熔解曲线法，基于多重巢式 PCR 扩增和熔解曲线分析技术，对经机械研磨破碎后的样本进行检测分析。多重巢式 PCR 扩增结合熔解曲线分析技术提高了检测试剂盒的反应灵敏度和特异性，系统软件自动评估数据并报告结果。

该产品检测鉴定CSF中14 种潜在中枢神经系统感染相关病原体，可在1小时左右获得检测结果，加快了脑炎脑膜炎的病原学诊断，从而可尽早开展针对性的临床治疗，降低了脑炎脑膜炎等疾病给患者带来的负担。

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。

（2022-08-05）

NMPA Announcement on Issuing Documents Including the Requirements for Preliminary Review of Registration Items of Medical Devices (2022 No. 40)

In order to further deepen the reform of review and approval system and encourage the innovation of medical devices, the current documents including the *Requirements for Preliminary Review of Registration Items of Medical Devices (Interim)* have been comprehensively revised by NMPA, in accordance with relevant requirements such as the *Provisions for Medical Device Registration and Filing* (SAMR Decree No. 47), *Provisions for In-Vitro Diagnostic Reagent Registration and Filing* (SAMR Decree No. 48), *NMPA Announcement on Publishing the Requirements for Application Dossiers and the Format of Approval Documents for Medical Device Registration* (2021 No. 121), *NMPA Announcement on Publishing the Requirements for Application Dossiers and the Format of Approval Documents for*

国家药监局关于发布《医疗器械产品注册项目立卷审查要求》等文件的通告（2022年第40号）

为进一步深化审评审批制度改革，鼓励医疗器械创新，按照《医疗器械注册与备案管理办法》（国家市场监督管理总局令第47号）、《体外诊断试剂注册与备案管理办法》（国家市场监督管理总局令第48号）、《国家药品监督管理局关于公布医疗器械注册申报资料要求和批准证明文件格式的公告》（2021年第121号）、《国家药品监督管理局关于公布体外诊断试剂注册申报资料要求和批准证明文件格式的公告》（2021年第122号）和《国家药品监督管理局关于实

In-Vitro Diagnostic Reagent Registration (2021 No. 122) and *NMPA Announcement on Implementing the Provisions for Medical Device Registration and Filing and Provisions for In-Vitro Diagnostic Reagent Registration and Filing* (No. 76, 2021) and other relevant requirements.

The Center for Medical Device Evaluation of NMPA shall review the corresponding application dossiers in the acceptance process in accordance with the revised requirements for preliminary review, and assess the completeness, compliance and consistency of the application dossiers for entering the technical review process. The preliminary review does not analyze the rationality and adequacy of the evaluation of product safety and effectiveness, and does not assess and determine the risk-benefit ratio of the product. The preliminary review is applicable to medical device registration, change of licensed items, review and approval of clinical trials and other application items.

The revised documents are issued on August 26, 2022 and shall come into force on the date of issuance, and the *NMPA Announcement on Issuing Documents Including the Requirements for Preliminary Review of Registration Items of Medical Devices (Interim) (2019 No. 42)* shall be abolished simultaneously.

(August 31,2022)

施〈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〉有关事项的通告》（2021年第76号）等有关要求，国家药品监督管理局组织对现行的《医疗器械产品注册项目立卷审查要求（试行）》等文件进行了全面修订。

国家药品监督管理局医疗器械技术审评中心在受理环节按照修订后的立卷审查要求对相应申请的申报资料进行审查，对申报资料进入技术审评环节的完整性、合规性、一致性进行判断。立卷审查不对产品安全性、有效性评价的合理性、充分性进行分析，不对产品风险受益比进行判定。立卷审查适用于医疗器械注册、许可事项变更、临床试验审批等申请事项。

修订后的文件于2022年8月26日发布并实施，《国家药监局关于发布〈医疗器械产品注册项目立卷审查要求（试行）〉等文件的通告》（2019年第42号）同时废止。

（2022-08-31）

NMPA Announcement on Issuing the Guidelines for the Inspection of the Quality Management System for Medical Device Registration(2022 No.50)

In order to effectively carry out the inspection of the quality management system for registration under the medical device registrant system and improve the inspection quality of the quality management system for medical device registration, in accordance with the *Regulations on Supervision and Administration of Medical Devices* (State Council Decree No. 739), *Provisions for Medical Device Registration and Filing* (SAMR Decree No. 47), *Provisions for In-vitro Diagnostic Reagent Registration and Filing* (SAMR Decree No. 48), Provisions for Supervision and Administration of Medical Device Manufacturing (SAMR Decree No. 53) and other requirements, NMPA organized to revise the *Guidelines for the Inspection of the Quality Management System for Medical Device Registration*, which is issued on September 29, 2022 and shall take effect as of the date of issuance. *NMPA Announcement on Issuing the Guidelines for the Inspection of the Quality Management System for Medical Device Registration* (2020 No. 19) shall be abolished simultaneously.

(October 10,2022)

国家药监局关于发布医疗器械注册质量管理体系核查指南的通告（2022年第50号）

为做好医疗器械注册人制度下注册质量管理体系核查工作，提高医疗器械注册质量管理体系核查工作质量，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）、《医疗器械生产监督管理办法》（市场监管总局令第53号）等要求，国家药品监督管理局组织修订了《医疗器械注册质量管理体系核查指南》，于2022年9月29日发布并实施。国家药品监督管理局《关于发布医疗器械注册质量管理体系核查指南的通告》（2020年第19号）同时废止。

（2022-10-10）

NMPA Announcement on Issuing the Key Inspection Points and Judgment Principles of Good Manufacturing Practice for Cosmetics (2022 No.90)

In order to standardize the licensing, supervision and inspection of cosmetics production and guide registrants, filing applicants and entrusted manufacturers of cosmetics to implement the *Good Manufacturing Practice for Cosmetics*, in accordance with the *Regulations on Supervision and Administration of Cosmetics*, the *Provisions for Supervision and Administration of Manufacturing and Marketing of Cosmetics* and other regulations and rules, NMPA organized to formulate the *Key Inspection Points and Judgment Principles of the Good Manufacturing Practice for Cosmetics*, which are issued on October 20, 2022 and shall come into force on December 1, 2022. Relevant matters are announced as follows:

I. The department responsible for drug supervision and administration shall, in accordance with the *Good Manufacturing Practice for Cosmetics*, the *Key Inspection Points and Judgment Principles of the Good Manufacturing Practice for Cosmetics*, carry out inspection on cosmetics registrants, filing entities and contract manufacturers (hereinafter collectively referred to as "the enterprise"), and comprehensively judge the implementation of the *Good Manufacturing Practice for Cosmetics* by enterprises.

II. For the enterprises judged as having "defects in the production quality management system" in the inspection, the department responsible for drug supervision and administration shall urge them to complete the rectification and submit the rectification report within the specified time limit, and organize on-site inspection when necessary. Where the enterprise commits a minor illegal act without causing harmful consequences and meets the requirements of the *Good Manufacturing Practice for Cosmetics* after rectification, it shall not be given an administrative penalty in accordance with the law.

III. For the enterprise judged as having "serious defects in the production quality management system" in the inspection, the department responsible for drug supervision and administration shall, in accordance with Article 54 of the *Regulation on Supervision and Administration of Cosmetics*, take emergency control measures such as ordering the suspension of production and operation to control product risks in a timely manner. The enterprise shall complete rectification within the specified time limit and submit rectification report to the department responsible for drug supervision and administration. The department responsible for drug supervision and administration shall conduct on-site re-inspection on the enterprise, and not resume its production or marketing until the rectification meets the requirements.

IV. For the enterprise judged as having "serious defects in the production quality management system" in the inspection, the department responsible for drug supervision and administration shall file an investigation in accordance with Article 60 (3) of the *Regulation on the Supervision and Administration of Cosmetics*, Article 59 of the *Provisions for Supervision and Administration of Manufacturing and Marketing of Cosmetics*, and other provisions.

(October 25, 2022)

国家药监局关于发布《化妆品生产质量管理规范检查要点及判定原则》的公告（2022年第90号）

为规范化妆品生产许可和监督检查工作，指导化妆品注册人、备案人、受托生产企业贯彻执行《化妆品生产质量管理规范》，根据《化妆品监督管理条例》及《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检查要点及判定原则》，于2022年10月20 公布，自2022年12月1日起施行。有关事项公告如下：

一、 负责药品监督管理的部门依据《化妆品生产质量管理规范》《化妆品生产质量管理规范检查要点及判定原则》对化妆品注册人、备案人、受托生产企业（以下统称为“企业”）开展检查，并对企业执行《化妆品生产质量管理规范》的情况进行综合判定。

二、对检查判定为“生产质量管理体系存在缺陷”的企业，负责药品监督管理的部门应当督促其在规定时间内完成整改并提交整改报告，必要时可以组织现场复查。企业违法行为轻微，没有造成危害后果，整改后符合《化妆品生产质量管理规范》要求的，依法不予行政处罚。

三、对检查判定为“生产质量管理体系存在严重缺陷”的企业，负责药品监督管理的部门应当依据《化妆品监督管理条例》第五十四条的规定，采取责令暂停生产、经营等紧急控制措施，及时控制产品风险。企业应当在规定的时间内完成整改，并向负责药品监督管理的部门提交整改报告。负责药品监督管理的部门应当对企业进行现场复查，确认整改符合要求后，方可恢复其生产、经营。

四、对检查判定为“生产质量管理体系存在严重缺陷”的企业，负责药品监督管理的部门应当根据《化妆品监督管理条例》第六十条第（三）项、《化妆品生产经营监督管理办法》第五十九条等规定立案调查。

（2022-10-25）

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)

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）

New Version of Measures for Supervision and Administration of Drug Recall Shall Come into Force on November 1

On October 26, NMPA issued the newly revised *Measures for Supervision and Administration of Drug Recall* (hereinafter referred to as the *Measures*), which shall come into force on November 1.

In order to better implement the *Drug Administration Law of the People's Republic of China and the Vaccine Administration Law of the People's Republic of China*, NMPA organized to revise the *Measures* issued and implemented in 2007, and issued and implemented them in the form of announcement after the former *Measures* were abolished by SAMR. The new version of the *Measures*, in combination with the actual development of the industry, adheres to the principles of risk management and whole-process management and control, focuses on timely control of quality problems or other potential safety hazards, optimizes the implementation procedures for investigation and evaluation and recall, scientifically improves the handling measures for recalled drugs, compacts the responsibilities of marketing authorization holders (hereinafter referred to as MAH), and thus urges MAHs to proactively eliminate possible potential safety hazards of drugs in the embryonic or initial stage and better ensure the drug safety of the public.

The new version of the *Measures* includes 33 articles in five chapters including the General Provisions, Investigation and Evaluation, Voluntary Recall, Mandatory Recall and Supplementary Provisions. It is clarified that MAHs are the main body of responsibility for controlling risks and eliminating potential hazards, and drug manufacturers, drug distributors and drug user units shall actively assist in the recall of prepared slices of Chinese crude drugs and TCM granules in prescription, and their manufacturers shall organize the implementation in accordance with the new

新版《药品召回管理办法》11月1日起施行

10月26日，国家药监局发布新修订《药品召回管理办法》（以下简称《办法》），自11月1日起施行。

为更好地贯彻落实《中华人民共和国药品管理法》《中华人民共和国疫苗管理法》，国家药监局组织对2007年发布实施的《办法》进行了修订，并在市场监管总局废止原《办法》后，以公告形式发布实施。新版《办法》结合行业发展实际，坚持风险管理、全程管控原则，围绕及时控制质量问题或者其他安全隐患，优化调查评估和召回实施程序，科学完善召回药品处理措施，压实药品上市许可持有人（以下称持有人）责任，从而督促持有人主动将可能的药品安全隐患消除在萌芽或初起阶段，更好地保障公众用药安全。

新版《办法》包括总则、调查与评估、主动召回、责令召回、附则等五章共33条。明确持有人是控制风险和消除隐患的责任主体，药品生产企业、药品经营企业、药品使用单位应当积极协助，对于中药饮片、中药配方颗粒的召回，其生产企业按照新版《办法》组织实施。新版《办法》完善了持有人

version of the *Measures*. The new version of the *Measures* improves the investigation and evaluation requirements for the drugs with possible quality problems or other potential safety hazards by MAHs, refines the implementation procedure for voluntary recall by MAHs, urges and guides MAHs to promptly and voluntarily recall the drugs with quality problems or other potential safety hazards, and effectively fulfill the obligations of whole-life cycle management of drugs.

According to the provisions of the new version of the *Measures*, MAHs shall voluntarily release the drug recall information in accordance with the law. For those implementing Class I and Class II recalls, MAHs shall also apply for releasing the recall information in accordance with the law on the website of the local provincial drug regulatory authorities. The drug recall information released by the provincial drug regulatory authorities shall be linked to the website of NMPA. The legal disclosure of drug recall information is conducive to all sectors of society to promptly, objectively and accurately understand the quality problems or other potential safety hazards of drugs, and assist and supervise MAHs to implement drug recall in accordance with laws and regulations.

The new version of the *Measures* scientifically improves the handling measures for recalled drugs, clarifies that the marks and storage measures of recalled drugs should be significantly different from normal drugs to prevent errors and confusion; for those requiring destruction, they should be destroyed under the supervision of MAHs, drug manufacturers or drug regulatory authorities or notary institutions of the people's governments at or above the county level where the recalled drugs are stored; for those that can eliminate potential hazards by changing labels, revising and improving package inserts, re-packaging and other means, or for prepared slices of Chinese crude drugs that do not meet the drug standards but do not affect the safety and effectiveness, and can solve the problem through rework, they can be appropriately handled and then marketed. This appropriately reduces the burden on enterprise on the premise of adhering to the bottom line of safeguarding drug safety.

The new version of the *Measures* makes specific provisions for overseas MAHs to carry out recalls. Where the recall of drugs manufactured overseas involves the implementation within the territory of China, the agent designated by the overseas MAHs within the territory of China shall organize the implementation in accordance with the new version of the *Measures*. Where an overseas MAH implements a drug recall overseas and falls under relevant circumstances after comprehensive assessment, its agent in China shall report to the local provincial drug regulatory authority. The overseas MAH shall assess and determine the implementation of recall overseas, and if it is necessary to recall the drug within the territory of China, its agent in China shall organize the implementation in accordance with the new version of the *Measures*.

The new version of the *Measures* also clarifies the recall of drugs manufactured and exported domestically. Where domestic MAHs are required to find that the exported drugs have quality problems or other potential safety hazards, they shall promptly notify the drug regulatory authorities and purchasers of the importing country (region). Where they need to implement the recall overseas, they shall organize the implementation of the recall in accordance with the relevant laws and regulations of the importing country (region) and the provisions of the procurement contract.

The new version of the *Measures* specifies the management and guidance responsibilities of drug regulatory authorities at all levels for drug recall in accordance with the law. Provincial drug regulatory authorities shall order MAHs to recall those that shall be recalled by law but not yet recalled. Where a MAH refuses to recall, or a drug manufacturer, distributor or user fails to cooperate with the recall, the corresponding provincial drug regulatory authority shall investigate and punish it in accordance with Article 135 of the *Drug Administration Law*. (October 26, 2022)

对可能存在质量问题或者其他安全隐患药品的调查评估要求，细化了持有人主动召回实施程序，督促和指导持有人对存在质量问题或者其他安全隐患药品及时主动召回，切实履行药品全生命周期管理义务。

按照新版《办法》规定，持有人应当依法主动公布药品召回信息，对实施一级、二级召回的，还应当申请在所在地省级药品监管部门网站依法发布召回信息，省级药品监管部门发布的药品召回信息应当与国家药监局网站链接。药品召回信息的依法公开，有利于社会各界及时、客观、准确了解药品存在的质量问题或者其他安全隐患，协助和监督持有人依法依规实施药品召回工作。

新版《办法》科学完善召回药品处理措施，明确了召回药品标识、存放措施等应当与正常药品明显区别，防止差错、混淆；对需要销毁的，应当在持有人、药品生产企业或者储存召回药品所在地县级以上人民政府药品监管部门或者公证机构监督下销毁；对可以通过更换标签、修改并完善说明书、重新外包装等方式消除隐患的，或者对不符合药品标准但尚不影响安全性、有效性的中药饮片，且通过返工等能够解决该问题的，可以适当处理后再上市。这在坚守药品安全底线的基础上，合理减轻了企业负担。

对于境外持有人实施召回，新版《办法》予以具体规定。境外生产药品涉及在境内实施召回的，由境外持有人指定的中国境内代理人按照新版《办法》组织实施。境外持有人在境外实施药品召回，经综合评估后属于相关情形的，由其境内代理人向所在地省级药品监管部门报告，境外持有人要研判境外实施召回情况，如需在中国境内召回的，也应当由其境内代理人按照新版《办法》组织实施。

新版《办法》还对境内生产并出口药品的召回工作进行了明确。要求境内持有人发现出口药品存在质量问题或者其他安全隐患的，应当及时通报进口国（地区）药品监管机构和采购方，需要在境外实施召回的，应当按照进口国（地区）有关法律法规及采购合同的规定组织实施召回。

新版《办法》依法明确各级药品监管部门对药品召回工作的管理和指导职责。省级药品监管部门对持有人依法应当召回而未召回的，应当责令持有人召回。对持有人拒不召回的，药品生产企业、药品经营企业、药品使用单位不配合召回的，相应省级药品监管部门应当按照《药品管理法》第一百三十五条的规定进行查处。

（2022-10-26）

NMPA Announcement on Revising Package Insert of Domperidone Preparations (2022 No. 93)

According to the evaluation results of adverse drug reactions, in order to further ensure the medication safety of the public, NMPA decided to uniformly revise the package inserts of domperidone preparations (including domperidone tablets, domperidone dispersible tablets, domperidone orally disintegrating tablets, domperidone capsules, domperidone suspension, domperidone maleate tablets). The relevant matters are hereby announced as follows:

I. The marketing authorization holders of the aforesaid drugs shall, in accordance with the *Provision for Drug Registration* and other relevant provisions, and in accordance with the revision requirements for domperidone preparations, report them to the Center for Drug Evaluation of the NMPA or the provincial drug regulatory authorities for filling before January 24, 2023.

Where the revised content involves drug labels, it shall be revised together, and the instructions and other contents of labels shall be consistent with the original approved content. The original package inserts should no longer be used for drug products which are manufactured since the date of filing. The marketing authorization holder shall replace the package inserts and labels of the released drugs within 9 months after filing.

II. The marketing authorization holders shall carry out in-depth study on the mechanism of newly added adverse reactions, take effective measures to carry out publicity and training on drug use and safety issues, and guide physicians and pharmacists to use drugs rationally.

III. Clinicians and pharmacists shall carefully read the revised contents of the aforesaid package inserts, and conduct a full benefit/risk analysis according to the newly revised package inserts when selecting medication.

IV. Patients should carefully read the package insert before medication, and use prescription drugs in strict accordance with the doctor's advice.

V. Provincial drug regulatory authorities shall urge the MAHs of the aforesaid drugs within their respective administrative regions to do a good job in the revision of the corresponding instructions and the replacement of labels and package inserts as required, and severely investigate and punish the violations of laws and regulations in accordance with the law.

(October 27, 2022)

国家药监局关于修订多潘立酮制剂说明书的公告（2022年第93号）

根据药品不良反应评估结果，为进一步保障公众用药安全，国家药品监督管理局决定对多潘立酮制剂（包括多潘立酮片、多潘立酮分散片、多潘立酮口腔崩解片、多潘立酮胶囊、多潘立酮混悬液、马来酸多潘立酮片）说明书内容进行统一修订。有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照多潘立酮制剂修订要求，于2023年1月24日前报国家药品监督管理局药品审评中心或省级药品监督管理部门备案。

修订内容涉及药品标签的，应当一并进行修订，说明书及标签其他内容应当与原批准内容一致。在备案之日起生产的药品，不得继续使用原药品说明书。药品上市许可持有人应当在备案后9个月内对已出厂的药品说明书及标签予以更换。

二、药品上市许可持有人应当对新增不良反应发生机制开展深入研究，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，在选择用药时，应当根据新修订说明书进行充分的获益/风险分析。

四、患者用药前应当仔细阅读药品说明书，使用处方药的，应严格遵医嘱用药。

五、省级药品监督管理部门应当督促行政区域内上述药品的药品上市许可持有人按要求做好相应说明书修订和标签、说明书更换工作，对违法违规行为依法严厉查处。

（2022-10-27）

CFDI Announcement on Issuing the Guidelines for Manufacturing and Quality Management of Cell Therapy Products (Interim) (2022 No. 4)

In order to guide the MAHs to standardize manufacturing and quality management of cell therapy products and ensure product quality, the Center for Food and Drug Inspection of NMPA organized to draft the *Guidelines for the Production and Quality Management of Cell Therapy Products (Interim)*, which are hereby issued and implemented on October 28, 2022.

(October 31, 2022)

国家药品监督管理局食品药品审核查验中心关于发布《细胞治疗产品生产质量管理指南（试行）》的通告（2022年 第4号）

为指导药品上市许可持有人规范开展细胞治疗产品的生产和质量管理，保证产品质量，核查中心组织研究起草了《细胞治疗产品生产质量管理指南（试行）》，于2022年10月28日发布并执行。（2022-10-31）

NMPA Announcement on Suspending the Import, Sales and Use of Dutasteride Soft Capsules from GlaxoSmithKline (Ireland) Limited (2022 No. 96)

Recently, NMPA organized overseas off-site inspection on GlaxoSmithKline (Ireland) Limited, and the variety inspected was Dutasteride Soft Capsules (English name: Dutasteride Soft Capsules; registration certificate No.: H20160515; manufacturing address: Ul.Grunwaldzka 189, 60-322 Poznan, Poland). It was found in the inspection that the enterprise failed to conduct lot-by-lot and full-item inspection on the products exported to China in accordance with the registration standards, and had shortcomings in the prevention and control of microbial contamination risks. The comprehensive evaluation conclusion was that the production quality management of this variety did not meet the requirements of the *Good Manufacturing Practice for Drugs* (2010 Revision) in China.

According to the relevant provisions of the *Drug Administration Law of the People's Republic of China*, NMPA decided to suspend the import, sales and use of Dutasteride Soft Capsules from GlaxoSmithKline (Ireland) Limited since October 28, 2022. The drug regulatory authorities at all drug import ports shall suspend the issuance of Drug Import Note for the above product.

(October 31,2022)

国家药监局关于暂停进口、销售和使用GlaxoSmithKline（Ireland）Limited度他雄胺软胶囊的公告（2022年第96号）

近期，国家药监局组织对GlaxoSmithKline（Ireland）Limited开展药品境外非现场检查，检查品种为度他雄胺软胶囊（英文名称：Dutasteride Soft Capsules；注册证号：H20160515；生产地址：Ul.Grunwaldzka 189，60-322 Poznan，Poland）。检查发现，企业对出口中国的产品未按照注册标准进行逐批、全项检验，且在微生物污染风险防控方面存在不足，综合评定结论为该品种的生产质量管理不符合我国《药品生产质量管理规范》（2010年修订）要求。

根据《中华人民共和国药品管理法》有关规定，国家药监局决定，自 2022年10月28日起暂停进口、销售、使用GlaxoSmithKline（Ireland）Limited度他雄胺软胶囊。各药品进口口岸药品监督管理部门暂停发放上述产品的进口通关单。

（2022-10-31）

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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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