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中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

National Working Conference on Drug Registration and Post-marketing Administration Held in Beijing

From January 17 to 18, 2019, the National Working Conference on Drug Registration and Post-marketing Administration was held in Beijing. Guided by Xi Jinping's Thought on Socialism with Chinese Characteristics for a New Era, the Conference thoroughly studied the CPC Central Committee and the State Council's decisions and arrangements on drug administration, and the guidelines set forth in the National Working Conference on Drug Administration; and summed up the drug registration and post-marketing administration in 2018. The Conference deployed the key tasks for drug registration administration in 2019 as follows:

Improve the laws and regulations and standards system for drug registration, expedite the development, formulation and revision of a series of rules and regulations such as the Provisions for Drug Registration, and further the compilation of the Chinese Pharmacopoeia (2020 Edition); Deepen the reform of drug review and approval system, improve the implied licensing for drug clinical trials, further enhance the management ability for drug clinical trials and drug clinical research level; Fully promote classification-based consistency evaluation of generic drugs while securing the accessibility of pharmaceuticals, ensure consistent review standards, and further improve the relevant evaluation requirements and guidelines; Reinforce the supervision of drug R&D, improve the management of on-site inspection in drug registration, strengthen the organic integration of review, testing and inspection, while cracking down on data fraud and ensuring the authenticity of drug research.

Meanwhile, the Conference also clarified the key tasks of post-marketing supervision of drugs in 2019: Complying with the promulgation and implementation of the amendments to the Drug Administration Law, promote the development, formulation and revision of a series of Administrative Measures for drug production, distribution, random inspection and adverse reaction monitoring; Clarify the administrative powers, refine the regulatory process, highlight regulatory cooperation, and explore the establishment of life-cycle supervision mechanism for drugs; Intensify vaccine supervision, promote the cultivation of professional drug inspectors, strengthen the management of Vaccine Lot Release, reinforce the inspections over vaccine manufacturers, and designate special superintendent agencies to urge to handling of vaccine-related illegal cases; Consolidate drug sampling inspection and adverse reaction monitoring, and supervision over online drug sales as well as high-risk drug varieties; Promote the construction of informational traceability system to improve supervision efficiency; 5. Integrate inspections with audits, establish joint working mechanism, integrate administrative law enforcement with criminal justice to mete out severe punishments for malpractices. (January 21, 2019)

全国药品注册管理和上市后监管工作会议在京召开

2019年1月17日至18日，全国药品注册管理和上市后监管工作会议在京召开。会议以习近平新时代中国特色社会主义思想为指引，深入贯彻党中央国务院关于药品监管工作决策部署，贯彻落实全国药品监督管理工作会议精神，总结2018年药品注册管理和上市后监管工作，部署2019年工作任务。

会议就2019年药品注册管理重点工作进行了部署：完善药品注册法规标准体系，加快推进《药品注册管理办法》等一系列规章制度的制修订，继续推进《中国药典》（2020年版）编制工作；深化药品审评审批制度改革，完善药品临床试验默示许可，进一步提高药物临床试验管理能力和药物临床研究水平；全力推进仿制药一致性评价，坚持标准不降低，进一步完善相关评价要求和指导原则，在保障药品可及性的基础上，分类推进；加强药物研制环节监管，完善药品注册现场检查管理，强化审评与检查检验工作的有机衔接，严厉打击数据造假，确保药物研究的真实性。

会议同时明确了2019年药品上市后监管的重点任务：结合《药品管理法》修正案的颁布实施，推进药品生产、流通、抽查检验、不良反应监测等一系列监督管理办法的制修订；明确监管事权、细化监管流程、突出监管协作，探索建立药品全生命周期监管工作机制；强化疫苗监管，推动职业化药品检查员队伍建设，强化疫苗批签发管理，加大对疫苗生产企业检查力度，挂牌督办疫苗违法案件；强化药品抽检和不良反应监测，强化网络售药监管，强化对高风险品种监管；推进信息化追溯体系建设，提升监管效率；融合检查和稽查工作，建立协调联动机制，用好行刑衔接，严惩重处违法行为。(2019-01-21)

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National Working Conference on Medical Device Administration Held in Beijing

From January 21 to 22, 2019, the National Working Conference on Medical Device Administration was held in Beijing. Guided by Xi Jinping's Thought on Socialism with Chinese Characteristics for a New Era, the Conference studied the guidelines set forth in the National Working Conference on Drug Administration, summarized the related work in 2018, analyzed the current situation, and deployed the key tasks for medical device administration in 2019.

The Conference deployed five key tasks in 2019, namely: 1. Highlight innovation-driven administration to improve the quality of development. It is necessary to actively promote the development of innovative medical devices, solidly promote innovation in clinical trial management, and steadily advance the Registrant Pilot System. 2. Intensify risk control to safeguard the safety bottom line. It is necessary to highlight unannounced inspections, targeted sampling, systematic monitoring, effective governance, and deterrence of penalty. 3. Reinforce system construction and enhance regulatory capacity. It is necessary to improve the systems for laws and regulations, technical standards, technical support, and information technology-based supervision. 4. Consolidate the implementation of responsibilities and enhance the synergy of supervision forces. It is necessary to implement the principal responsibility of enterprises, the territorial management responsibility of local authorities, and the supervision responsibility of departments. 5. Strengthen scientific supervision and improve the level of supervision. It is necessary to promote the research on scientific administration, innovate regulatory operational mechanisms, and enhance international exchanges and cooperation. (January 23, 2019)

全国医疗器械监督管理工作会议在京召开

2019年1月21至22日，全国医疗器械监督管理工作会议在京召开。会议以习近平新时代中国特色社会主义思想为指导，贯彻落实2019年全国药品监督管理工作会议精神，总结2018年医疗器械监管工作，分析当前形势，部署2019年医疗器械监管重点工作。

会议部署了2019年五项重点工作，一是强化创新引领，提升发展质量。要积极推进创新医疗器械发展，扎实推进临床试验管理创新，稳步推进注册人制度试点。二是强化风险治理，筑牢安全底线。要突出检查的突击性、抽检的靶向性、监测的系统性、治理的实效性和惩治的威慑力。三是强化体系建设，提升监管能力。要完善法规制度体系、技术标准体系、技术支撑体系，推进信息化监管。四是强化责任落实，增强监管合力。要压实企业主体责任，落实属地管理责任，夯实部门监管责任。五是强化科学监管，提升监管水平。要推进监管科学研究，创新监管运行机制，加强国际交流合作。 (2019-01-23)

Regulations on the Professional Qualification System for Licensed Pharmacists and *Measures for Implementing Professional Qualification Examination of Licensed Pharmacists*

On March 18, 2019, NMPA and the Ministry of Human Resources and Social Security jointly issued the *Regulations on the Professional Qualification System for Licensed Pharmacists* and *the Measures for Implementing Professional Qualification Examination of Licensed Pharmacists.*

The *Regulations* contains 35 Articles in 6 Chapters, namely: General Provisions, Examinations, Registration, Responsibility, Supervision and Management, and Supplementary Rules. The *Measures* contains a total of 11 Articles, which set clear requirements for the organization and implementation units, time, subjects, exemption conditions, periods, disciplines and other aspects of the Examination. (March 20, 2019)

《执业药师职业资格制度规定》《执业药师职业资格考试实施办法》发布

2019年3月18日，国家药品监督管理局、人力资源和社会保障部联合印发了《执业药师职业资格制度规定》和《执业药师职业资格考试实施办法》。

《执业药师职业资格制度规定》包含总则、考试、注册、职责、监督管理、附则六章，共计35条。《执业药师职业资格考试实施办法》共计11条，对执业药师职业资格考试的组织实施单位、考试时间、考试科目、免试条件、考试周期、考试纪律等均提出了明确要求。 (2019-03-20)

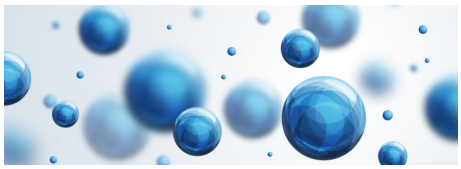
NMPA Issued the *Announcement on the Selection and Determination Procedures for Reference Formulations of Chemical Generic Drugs*

To standardize the review and consistency evaluation of generic drugs, optimize work procedures, strengthen service guidance, and ensure fairness, impartiality, and openness thereof, NMPA has organized the formulation of the *Procedures for the Selection and Determination of Reference Formulations of Chemical Generic Drugs*, which has

国家药品监督管理局发布《关于化学仿制药参比制剂遴选与确定程序的公告》

为规范仿制药审评和一致性评价工作，优化工作程序，强化服务指导，保证公平、公正、公开，国家药品监督管理局组织制

been released and in force on March 28, 2019, upon which the *Announcement on the Procedures for Filing and Recommendation of Reference Formulations for Consistency Evaluation of the Quality and Efficacy of Generic Drugs* (CFDA Announcement No. 99, 2016), promulgated by the former China Food and Drug Administration, has been repealed simultaneously. The relevant provisions of the present Announcement shall prevail over those previously announced, where discrepancies arise.. (March 28, 2019)



定了《化学仿制药参比制剂遴选与确定程序》，于2019年3月28日发布。

公告自发布之日起实施，原国家食品药品监督管理总局于2016年5月发布的《关于发布仿制药质量和疗效一致性评价参比制剂备案与推荐程序的公告》（2016年第99号）同时废止，原发布的参比制剂相关文件与本公告不一致的，以本公告为准。 (2019-03-28)

NMPA Issued the *Announcement on Revising the Package Inserts of Marsdenia Tenacissima Injection (Xiaoaiping Injection)*

In accordance with the results of the Adverse Drug Reaction Evaluation, to further protect drug safety for the people, on March 20, 2019, NMPA issued the *Announcement on Revising the Package Inserts of Marsdenia Tenacissima Injection (Xiaoaiping Injection)*, with decisions made to add warnings to the package inserts of Marsdenia Tenacissima Injection (Xiaoaiping Injection) and revise the Entries of [Adverse reactions], [Contraindications] and [Precautions] on its package inserts. (March 20, 2019)

国家药品监督管理局发布《关于修订通关藤注射液（消癌平注射液）说明书的公告》

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通关藤注射液（消癌平注射液）增加警示语，并对其药品说明书【不良反应】【禁忌】【注意事项】项进行修订，2019年3月20日，发布《关于修订通关藤注射液（消癌平注射液）说明书的公告》。 (2019-03-20)

NMPA Issued the *Announcement on Revising the Package Inserts of Secretio Bufonis Injection*

As per the results of ADR evaluation, to further protect the safety of public medication, NMPA released on March 18, 2019 the *Announcement on Revising the Package Inserts of Secretio Bufonis Injection*, with decision made to revise the Entries of [Warnings], [Adverse reactions], [Contraindications] and [Precautions] of the package inserts of Secretio Bufonis Injection. (March 20, 2019)

国家药品监督管理局发布《关于修订蟾酥注射液说明书的公告》

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蟾酥注射液药品说明书【警示语】【不良反应】【禁忌】和【注意事项】等项进行修订，2019年3月18日，发布《关于修订蟾酥注射液说明书的公告》。 (2019-03-18)

NMPA Issued the *Announcement on Revising the Package Inserts of Shangke Jiegu Tablets, Wenxin Preparations and Niuhuang Jiedu (Bezoar Detoxification) Preparations*

As per the results of ADR evaluation, to further protect the safety of public medication, NMPA decided to add warnings to the package inserts of Shangke Jiegu Tablets and Niuhuang Jiedu (Bezoar Detoxification) Preparations (tablets, pills, capsules, soft capsules), and revise the Entries of [Adverse reactions], [Contraindications] and [Precautions] of their package inserts as well as that of the Wenxin Preparations (granules, capsules, tablets), and released on March 8, 2019 the *Announcement on Revising the Package Inserts of Shangke Jiegu Tablest, Wenxin Preparation and Niuhuang Jiedu (Bezoar Detoxification) Preparations*.

(March 8, 2019)

家药品监督管理局发布《关于修订伤科接骨片、稳心制剂和牛黄解毒制剂说明书的公告》

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伤科接骨片和牛黄解毒制剂（片剂、丸剂、胶囊剂、软胶囊剂）增加警示语，并对其和稳心制剂（颗粒剂、胶囊剂、片剂）药品说明书【不良反应】、【禁忌】和【注意事项】等项进行修订，2019年3月8日，发布《关于修订伤科接骨片、稳心制剂和牛黄解毒制剂说明书的公告》。 (2019-03-08)

NMPA Issued the *Announcement on Revising the Package Inserts of Cefoperazone-Containing Drugs*

To further protect the safety of public medication, NMPA released on March 7, 2019 the *Announcement on Revising the Package Inserts of Cefoperazone-Containing Drugs*, with decisions made to revise the Entries of [Adverse reactions], [Contraindications], [Drug interactions] of the package inserts for cefoperazone-containing drugs (encompassing cefoperazone sodium for injection, cefoperazone sodium and sulbactam sodium for injection (1:1) and (2:1), cefoperazone sodium and tazobactam sodium for injection (4:1), and (8:1)) . (March 7, 2019)

国家药品监督管理局发布《关于修订含头孢哌酮药品说明书的公告》

为进一步保障公众用药安全，国家药品监督管理局决定对含头孢哌酮药品（包括注射用头孢哌酮钠、注射用头孢哌酮钠舒巴坦钠、注射用头孢哌酮钠舒巴坦钠（1：1）、注射用头孢哌酮钠舒巴坦钠（2：1）、注射用头孢哌酮钠他唑巴坦钠、注射用头孢哌酮钠他唑巴坦钠（4：1）、注射用头孢哌酮钠他唑巴坦钠（8：1）说明书【不良反应】、【禁忌】、【药物相互作用】等项进行修订，2019年3月7日，发布《关于修订含头孢哌酮药品说明书的公告》。 (2019-03-07)

NMPA Issued the *Announcement on Revising the Package Inserts of Amoxicillin (Sodium) Clavulanate Potassium Preparations*

To further protect the safety of public medication, NMPA released on March 7, 2019 the Announcement on Revising the Package Inserts of Amoxicillin (Sodium) Clavulanate Potassium Preparations, with decisions made to revise the Entries of [Adverse reactions], [Contraindications], [Precautions], etc. of amoxicillin (sodium) clavulanate potassium preparations (including injections, tablets, suspensions, granules and capsules) . (March 7, 2019)

国家药品监督管理局发布《关于修订阿莫西林（钠）克拉维酸钾制剂说明书的公告》

为进一步保障公众用药安全，国家药品监督管理局决定对阿莫西林（钠）克拉维酸钾制剂（包括注射剂、片剂、混悬剂、颗粒剂和胶囊剂）说明书【不良反应】、【禁忌】、【注意事项】等项进行修订，2019年3月7日，发布《关于修订阿莫西林（钠）克拉维酸钾制剂说明书的公告》。 (2019-03-07)

NMPA Issued the *Announcement on the Conversion of Three OTC Drugs Including Weitongning Tablets into Prescription Drugs and the Revision of Corresponding Package Inserts*

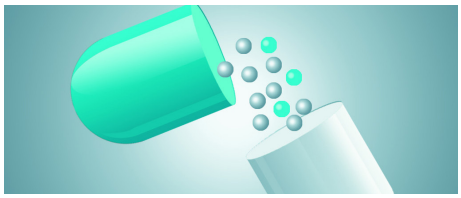
To protect the safety of public medication, according to the *Regulations for the Classification Management of Prescription and Non-prescription Drugs (Interim)*, NMPA issued an Announcement on March 4, 2019, to delist from the Over-the-counter Drug List the Weitongning Tablets, HuaZhi (hemorrhoid-eliminating) Suppository and de-thrombosis and collaterals-dredging preparations (tablets, capsules, granules), which shall thence be managed as prescription drugs. The package inserts of the above-mentioned drugs shall be revised simultaneously. (March 4, 2019)

国家药品监督管理局发布《关于胃痛宁片等3种药品转换为处方药并修订药品说明书的公告》

为保障公众用药安全，根据《处方药与非处方药分类管理办法（试行）》的规定，2019年3月4日，国家药品监督管理局发布公告，将胃痛宁片、化痔栓及消栓通络制剂（片剂、胶囊剂、颗粒剂）调出非处方药目录，按处方药管理，同时对上述药品说明书进行修订。 (2019-03-04)

NMPA Issued the *Announcement on Revising the Package Inserts of GuCi (Bone Spur) Capsules and Tablets*

As per the results of ADR evaluation, to further protect the safety of public medication,



NMPA released on March 12, 2019 the *Announcement on Revising the Package Inserts of GuCi (Bone Spur) Capsules and Tablets*, with decision made to revise the Entries of [Warnings], [Adverse reactions], [Contraindications] and [Precautions] of the package inserts of GuCi (Bone Spur) Capsules and Tablets. (March 12, 2019)

国家药品监督管理局发布《关于修订骨刺胶囊和骨刺片说明书的公告》

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骨刺胶囊和骨刺片药品说明书【警示语】、【不良反应】、【禁忌】和【注意事项】等项进行修订，2019年3月12日，发布《关于修订骨刺胶囊和骨刺片说明书的公告》。 (2019-03-04)

NMPA Issued the *Announcement on Adjusting the Management Categories for 12 Drugs Such as Bushen Runfei (Kidney Reinforcing and Lung Nourishing) Oral Liquid*

According to the *Regulations for the Classification Management of Prescription and Non-prescription Drugs (Interim)*, NMPA issued an Announcement on March 4, 2019 to convert 12 kinds of drugs, such as Bushen Runfei Oral Liquid, from prescription drugs to non-prescription drugs. The list of specific varieties and the Template of non-prescription drug package inserts are released at the same time.

(February 19, 2019)

国家药品监督管理局发布《关于调整补肾润肺口服液等12个药品管理类别的公告》

根据《处方药与非处方药分类管理办法（试行）》的规定，2019年2月19日，国家药品监督管理局发布公告，将补肾润肺口服液等12种药品由处方药转换为非处方药。具体品种名单及非处方药说明书范本一并发布。

(2019-02-19)

NMPA Issued the *Announcement on the Cessation of Production, Sale and Use of Furazolidone-Containing Compound Preparations*

On February 15, 2019, NMPA issued the *Announcement on the Cessation of Production, Sale and Use of Furazolidone-Containing Compound Preparations*, which reads as follows:

As per Article 42 of the Drug Administration Law of the People's Republic of China and Article 40 of the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, and NMPA re-evaluation, furazolidone-containing compound preparations are deemed as prone to serious adverse reactions, the risk of use outweighs its benefit in China. NMPA hereby decides to stop with immediate effect the production, sales and use of such preparations in China, and revoke the corresponding drug approval proof documents. The marketed furazolidone-containing preparations shall be recalled by the manufacturer responsible, the recall should be completed prior to March 31, 2019, and the recalled products shall be destructed under the supervision of the competent food and drug administration department. (February 15, 2019)

国家药品监督管理局发布《关于停止生产销售使用含呋喃唑酮复方制剂的公告》

2019年2月15日，国家药品监督管理局发布《关于停止生产销售使用含呋喃唑酮复方制剂的公告》，内容如下：

根据《中华人民共和国药品管理法》第四十二条和《中华人民共和国药品管理法实施条例》第四十条规定，经国家药品监督管理局组织再评价，认为含呋喃唑酮复方制剂存在严重不良反应，在我国使用风险大于获益，决定自即日起停止含呋喃唑酮复方制剂在我国的生产、销售和使用，撤销药品批准证明文件。已上市销售的含呋喃唑酮复方制剂由生产企业负责召回，召回工作应于2019年3月31日前完成，召回产品由企业所在地药品监督管理部门监督销毁。 (2019-02-15)

Medical Devices

NMPA Issued the *Notice on Reinforcing Supervision and Inspection of Sterile and Implantable Medical Devices*

To further strengthen the supervision and inspection of sterile and implantable medical devices, fully implement the principal responsibility of enterprises, secure the safety and effectiveness of medical devices, and ensure people's safe use of devices, in alignment with the work arrangement for 2019 medical device supervision, NMPA issued on March 27, 2019 the *Notice on Reinforcing Supervision and Inspection of Sterile and Implantable Medical Devices*, which covers the inspection targets, scope, focuses, methods and work requirements. (March 27, 2019)

医疗器械

国家药品监督管理局发布《关于进一步加强无菌和植入性医疗器械监督检查的通知》

为进一步加强无菌和植入性医疗器械监督检查，全面落实企业主体责任，保障医疗器械安全有效，保证公众用械安全，根据2019年医疗器械监管工作安排，2019年3月27日，国家药品监督管理局就进一步加强无菌和植入性医疗器械监督检查发布通知。通知包括：检查目标、检查范围、检查重点、检查方式和工作要求。 (2019-03-27)

NMPA Issued Guidelines for Technical Review of the Registration of Four Devices Including High-Frequency Ultrasound Ophthalmic Diagnostic Instrument

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, NMPA organized the formulation of the *Guidelines for Technical Review of the Registration of High-Frequency Ultrasound Ophthalmic Diagnostic Instrument, Guidelines for Technical Review of the Registration of Dual-Energy X-ray Bone Densitometers, Guidelines for Technical Review of the Registration of Anesthesia Machine, and Guidelines for Technical Review of the Registration of Oral and Maxillofacial Cone Beam Computed Tomography Equipment*, which have been promulgated on March 26, 2019. (March 26, 2019)

国家药品监督管理局发布眼科高频超声诊断仪注册技术审查指导原则等4项指导原则

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《眼科高频超声诊断仪注册技术审查指导原则》《双能X射线骨密度仪注册技术审查指导原则》《麻醉机注册技术审查指导原则》《口腔颌面锥形束计算机体层摄影设备临床评价指导原则》，于2019年3月26日发布。 (2019-03-26)

NMPA Issued Guidelines for Clinical Trials of Three Products Including Intraocular Lenses

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, NMPA organized the formulation of the *Guidelines for Clinical Trials of Intraocular Lenses, Guidelines for Clinical Trials of Sodium Hyaluronate Filling Materials for Facial Injection*, and *Guidelines for Clinical Trials of Ophthalmic Femtosecond Laser Treatment Machines for Corneal Flaps*, which have been promulgated on March 20, 2019.

(March 20, 2019)

国家药品监督管理局发布人工晶状体等3项临床试验指导原则

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《人工晶状体临床试验指导原则》《透明质酸钠类面部注射填充材料临床试验指导原则》《用于角膜制瓣的眼科飞秒激光治疗机临床试验指导原则》，于2019年3月20日发布。 (2019-03-20)

NMPA Issued the *Announcement on the Guidelines for Technical Review of the Registration of Four Detection Reagents Including Brain Natriuretic Peptide / Amino-Terminal Pro-Brain Natriuretic Peptide Detection Reagents*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA organized the formulation of the *Guidelines for Technical Review of the Registration of Brain Natriuretic Peptide / Amino-Terminal Pro-Brain Natriuretic Peptide Detection Reagents*, *Guidelines for Technical Review of the Registration of Total Thyroxine Detection Reagents*, *Guidelines for Technical Review of the Registration of Progesterone Detection Reagents*, and the *Guidelines for Technical Review of the Registration of Procalcitonin Detection Reagents*, which have been promulgated on March 13, 2019.

(March 13, 2019)

国家药品监督管理局发布《关于脑利钠肽／氨基末端脑利钠肽前体检测试剂等4项注册技术审查指导原则的通告》

为加强对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《脑利钠肽／氨基末端脑利钠肽前体检测试剂注册技术审查指导原则》《总甲状腺素检测试剂注册技术审查指导原则》《孕酮检测试剂注册技术审查指导原则》《降钙素原检测试剂注册技术审查指导原则》，于2019年3月13日发布。

（2019-03-13）

NMPA Issued Three Guidelines for Clinical Trials of Aortic Coated Stent-Graft Systems and Others

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, NMPA organized the formulation of the Guidelines for Clinical Trials of Aortic Coated Stent-Graft System, the *Guidelines for Clinical Trials of Bioabsorbable Coronary Artery Drug-Eluting Stents*, and *Guidelines for Clinical Trials of Transcatheter Implantable Artificial Aortic Valves*, which have been promulgated on March 1, 2019.

(March 1, 2019)

国家药品监督管理局发布主动脉覆膜支架系统等3项临床试验指导原则

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《主动脉覆膜支架系统临床试验指导原则》《生物可吸收冠状动脉药物洗脱支架临床试验指导原则》《经导管植入式人工主动脉瓣膜临床试验指导原则》，于2019年3月1日发布。（2019-03-01）

NMPA Issued the *Announcement on Approving the Issuance of the No. 1 Standard Amendment for Medical Device Industry Standard YY1298-2016 Medical Endoscope: Capsule Endoscope*

On January 29, 2019, NMPA approved the issuance of the No. 1 Standard Amendment for Medical Device Industry Standard YY1298-2016 *Medical Endoscope: Capsule Endoscope*, which takes effect upon the date of issuance. (January 29, 2019)

国家药品监督管理局发布《关于批准发布YY1298—2016《医用内窥镜胶囊式内窥镜》医疗器械行业标准第1号标准修改单的公告》

2019年1月29日，国家药品监督管理局批准发布YY1298—2016《医用内窥镜胶囊式内窥镜》医疗器械行业标准第1号修改单，自发布之日起实施。（2019-01-29）

General Information

VAT Discounts for the First Batch of Orphan Drugs Officially Landed

On February 22, 2019, the Ministry of Finance, the General Administration of Customs, the State Administration of Taxation and NMPA jointly issued the *Notice on VAT Policies for Orphan Drugs (hereinafter referred to as Notice)*, marking the official "Landing" of preferential VAT for the first batch of drugs for orphan diseases (orphan drugs) .

On February 11, Premier Li Keqiang presided over the Executive Meeting of the State Council and decided to grant VAT preferential treatment for drugs for orphan diseases. As from March 1st, the value-added tax for the first batch of 21 orphan-diseases drugs and 4 APIs shall, with reference to anticancer drugs, be reduced to 3% upon import, and the domestic link can opt for 3% in simplified method for calculating VAT.

The Notice pointed out that in order to encourage the development of the orphan diseases pharmaceutical industry and reduce the cost of drugs for patients, as from March 1, VAT general taxpayers can opt for calculating and paying VAT as per the simplified method at the 3% rate for manufacturing, wholesale and retail of orphan drugs. The taxpayer mentioned above shall not alter the tax payment method within 36 months after selecting the simplified method for VAT calculation and payment. As from March 1st, the VAT for imported orphan drugs shall be levied at a reduced level at 3%. Taxpayers should separately account for the sales of orphan drugs.

The orphan drugs referred in this Notice denote the preparations and APIs approved by NMPA for orphan diseases. According to the Notice, the first batch of orphan drugs covers 21 kinds of preparations such as Bosentan Tablets, Ambrisentan Tablets, Adempas (Riociguat) Tablets, human coagulation factor VIII, human prothrombin complex; and 4 APIs: bosentan, pirfenidone, penicillamine and riluzole.

The Notice clarified that the scope of orphan drugs shall be subject to dynamic adjustments determined, as appropriate, by the Ministry of Finance, the General Administration of Customs, the State Administration of Taxation, and NMPA.

(Source:China Pharmaceutical News February 25, 2019)

综合信息

首批罕见病药品增值税优惠正式落地

2019年2月22日，财政部、海关总署、税务总局和国家药品监管局4部门联合下发《关于罕见病药品增值税政策的通知》（以下简称“通知”），首批罕见病药品增值税优惠正式落地。

2月11日，国务院总理李克强主持召开国务院常务会议，决定对罕见病药品给予增值税优惠，从3月1日起，对首批21个罕见病药品和4个原料药，参照抗癌药对进口环节减按3%征收增值税，国内环节可选择按3%简易办法计征增值税。

通知指出，为鼓励罕见病制药产业发展，降低患者用药成本，自3月1日起，增值税一般纳税人生产销售和批发、零售罕见病药品，可选择按照简易办法依照3%征收率计算缴纳增值税。上述纳税人选择简易办法计算缴纳增值税后，36个月内不得变更。自3月1日起，对进口罕见病药品，减按3%征收进口环节增值税。纳税人应单独核算罕见病药品的销售额。

所谓罕见病药品，是指经国家药品监管部门批准注册的罕见病药品制剂及原料药。根据通知，首批罕见病药品包含波生坦片、安立生坦片、利奥西呱片、人凝血因子Ⅷ、人凝血酶原复合物等21种罕见病药品制剂，以及波生坦、吡非尼酮、青霉胺、利鲁唑4种罕见病药品原料药。

通知明确，罕见病药品范围实行动态调整，由财政部、海关总署、税务总局、国家药监局根据变化情况适时明确。

（摘自：中国医药报 2019-02-25）

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

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