2019. Volume 10

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

CPC Central Committee and the State Council Issued Opinions on Facilitating the Inheritance, Innovation and Development of Traditional Chinese Medicine

Recently, the Central Committee of the Communist Party of China and the State Council issued the *Opinions on Facilitating the Inheritance, Innovation and Development of Traditional Chinese Medicine* (hereinafter referred to as *Opinions*), proffering 20 suggestions from 6 aspects, namely: improving TCM service system; giving play to the unique role of TCM in maintaining and promoting people's health; vigorously promoting TCM quality enhancement and the high-quality development of TCM industry; strengthening the building of TCM talent team; facilitating the inheritance, openness and innovative development of TCM; reforming and ameliorating the management system and mechanism of TCM.

In terms of vigorously promoting TCM quality enhancement and the high-quality development of TCM industry, the *Opinions* purport to strengthen TCM quality control and revise the Good Agricultural Practice (GAP) for Chinese herbal medicine; explore, formulate and implement incentive policies for GAP of Chinese herbal medicine; and improve the third-party quality inspection system, etc. The *Opinions* also purport to promote quality enhancement of TCM slices and Chinese patent medicines, and expedite the revision of TCM Standard (Volume I) of the *Chinese Pharmacopoeia*; improve the standard system for TCM slices; explore the establishment of clinical value-oriented evaluation paths, and beef up TCM post-marketing evaluation. The *Opinions* noted that it is necessary to reform and improve the management of TCM registration, optimize the classification of TCM registration in a timely manner, formulate management regulations for TCM review and approval, implement prioritized review & approval system based on clinical value, and optimize and standardize the record-filing management of TCM preparations in medical institutions. To strengthen the supervision of the quality and safety of TCM, the *Opinions* clearly stated that it is necessary to implement the principal responsibility of TCM manufacturers, establish a multi-department collaborative supervision mechanism, and explore the establishment of a full-process traceability system for the production, distribution and use of Chinese herbal medicine, TCM slices and Chinese patent medicines; and reinforce the monitoring of adverse reactions of TCM injections.

(October 29, 2019)

中共中央 国务院印发促进中医药传承创新发展的意见

近日，中共中央 国务院印发《关于促进中医药传承创新发展的意见》（以下简称《意见》）。《意见》从健全中医药服务体系、发挥中医药在维护和促进人民健康中的独特作用、大力推动中药质量提升和产业高质量发展、加强中医药人才队伍建设、促进中医药传承与开放创新发展、改革完善中医药管理体制机制六方面提出20条意见。

在大力推动中药质量提升和产业高质量发展方面，《意见》指出，要加强中药材质量控制，修订中药材生产质量管理规范；探索制定实施中药材生产质量管理规范的激励政策；健全中药材第三方质量检测体系等。要促进中药饮片和中成药质量提升，加快修订《中华人民共和国药典》中药标准（一部）；健全中药饮片标准体系；探索建立以临床价值为导向的评估路径，加大中成药上市后评价工作力度。《意见》指出，要改革完善中药注册管理，及时完善中药注册分类，制定中药审评审批管理规定，实施基于临床价值的优先审评审批制度；优化和规范医疗机构中药制剂备案管理。对加强中药质量安全监管，《意见》明确，要落实中药生产企业主体责任，建立多部门协同监管机制，探索建立中药材、中药饮片、中成药生产流通使用全过程追溯体系；加强中药注射剂不良反应监测。

(2019-10-29)

NMPA Issued Announcement on Five Supplementary Test Methods Including Testing Items for Abietic Acid in Chenxianghuazhi Pills

As per the *Drug Administration Law of the People's Republic of China* and its implementing regulations, NMPA has approved and released on November 26, 2019 the *Supplementary Test Methods for Abietic Acid Test Items in Chenxianghuazhi Pills, Supplementary Test Methods for Triglochinic Acid Test Items in Pinellia ternata and Prepared Slices of Raw Pinellia, Rhizoma Pinelliae*

国家药品监督管理局发布关于沉香化滞丸中松香酸检查项等5项补充检验方法的公告

按照《中华人民共和国药品管理法》及其实施条例的有关规定，《沉香化滞丸中松香酸检查项补充检验方法》《半夏药材及饮片生半夏、法半夏、姜半夏、清半夏中水麦冬酸检查项补充检验方法》《妇舒丸中牛皮源成分检查

Published by
China Center for Food and Drug International Exchange
Servier (Tianjin) Pharmaceutical Co., Ltd.

Preparatum, Ginger Processed Pinellia, and Rhizoma Pinelliae Preparata, Supplementary Test Methods for Cowhide-Derived Component in Fushu Pills, Supplementary Test Methods for Auramine O Test Item in Lupao Powder, and Supplementary Test Methods for Stem and Leaf Test Items in Panax Notoginseng Powder.

(November 26, 2019)

项补充检验方法》《绿袍散中金胺O检查项补充检验方法》《三七粉中三七茎叶检查项补充检验方法》5项药品补充检验方法经国家药品监督管理局批准，于2019年11月26日发布。 (2019-11-26)

NMPA Released *Announcement on the Application of 13 ICH Guidelines Including S1A: Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals*

On November 12, 2019, NMPA issued the Announcement on the *Application of 13 ICH Guidelines Including S1A: Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals*, which reads as follows:

To keep pace with the international technical standards for drug registration, NMPA has decided after research to apply 13 ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines, including the *S1A: Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals*. The relevant matters are announced as follows:

1. Applicants must conduct research in accordance with the ICH Guidelines ASAP based on the current technical requirements; as from May 1, 2020, non-clinical studies (with start dates determined pursuant to the *Good Laboratory Practice for Non-Clinical Laboratory Studies*) shall apply to 13 ICH non-clinical guidelines.
2. Relevant technical guidelines can be found on the website of Center for Drug Evaluation, NMPA, who is responsible for related technical guidance in the implementation of this Announcement.

(November 12, 2019)

国家药品监督管理局发布关于适用《S1A：药物致癌性试验必要性指导原则》等13个国际人用药品注册技术协调会指导原则的公告

2019年11月12日，国家药品监督管理局发布关于适用《S1A：药物致癌性试验必要性指导原则》等13个国际人用药品注册技术协调会指导原则的公告》，内容如下：

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《S1A：药物致癌性试验必要性指导原则》等13个国际人用药品注册技术协调会（ICH）指导原则。现就有关事项公告如下。

一、申请人需在现行技术要求基础上尽早按照ICH指导原则开展研究；自2020年5月1日起开始的非临床研究适用13个ICH非临床指导原则，非临床研究起始日期的认定遵照《药物非临床研究质量管理规范》中相关规定执行。

二、相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。 (2019-11-12)

NMPA Released Announcement on the Application of 15 ICH Guidelines Including *E1: Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions*

On November 12, 2019, NMPA issued the Announcement on the Application of 15 ICH Guidelines Including *E1: Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions*, which reads as follows:

To keep pace with the international technical standards for drug registration, NMPA has decided after research to apply 15 ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Guidelines, including the *E1: Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions* (see annex for details). The relevant matters are announced as follows:

I. *E2F: Development Safety Update Report*

国家药品监督管理局发布关于适用《E1：人群暴露程度：评估非危及生命性疾病长期治疗药物的临床安全性》等15个国际人用药品注册技术协调会指导原则的公告

2019年11月12日，国家药品监督管理局发布关于适用《E1：人群暴露程度：评估非危及生命性疾病长期治疗药物的临床安全性》等15个国际人用药品注册技术协调会指导原则的公告。内容如下：

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《E1：人群暴露程度：评估非危及生命性疾病长期治疗药物的临床安全性》等15个国际人用药品注册技术协调会（ICH）指导原

and E2F Examples, E5 (R1): Ethnic Factors in the Acceptability of Foreign Clinical Data and E5 Q & A (R1), and *E17: General Principles for Planning and Design of Multiregional Clinical Trials* shall be applied as from the date of issuance of this Announcement.

2. For new drug marketing applications accepted 6 months after the date of this Announcement, *E3: Structure and Content of Clinical Study Reports* and *E3 Q & A (R1)* are applicable.
3. *E2E: Pharmacovigilance Planning* is applicable to new drug marketing applications accepted after 3 months from the date of this Announcement, and new drug marketing applications approved after 6 months from the date of this Announcement.
4. The relevant requirements for drug clinical research started 6 months after the issuance date of this Announcement shall apply the *E4: Dose-Response Information to Support Drug Registration, E7: Studies in Support of Special Populations: Geriatrics* and *E7 Q & A, E8: General Considerations for Clinical Trials, E9: Statistical Principles for Clinical Trials, E10: Choice of Control Group and Related Issues in Clinical Trials, E11 (R1): Clinical Investigation of Medicinal Products in the Pediatric Population, E15: Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding,* and *E16: Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions.*
5. Clinical trial applications approved 6 months after the date of issuance of this Announcement and new drug marketing applications accepted 3 years later shall apply to *E1: Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions.*
6. *E12A: Principles for Clinical Evaluation of New Antihypertensive Drugs* shall be applied to clinical trials for new antihypertensive drugs 6 months after the date of issuance of this Announcement, where the sample size of subjects required for safety assessment shall be based on the requirements of E1 schedule.

Relevant technical guidelines can be found on the website of Center for Drug Evaluation NMPA, who is responsible for related technical guidance in the implementation of this Announcement.

Attachment (omitted) .

(November 12, 2019)

则（详见附件）。现就有关事项公告如下。

一、本公告发布之日起适用《E2F：研发期间安全性更新报告》及《E2F示例》、《E5（R1）：接受国外临床试验数据的种族因素》及《E5问答（R1）》和《E17：多区域临床试验计划与设计的一般原则》。

二、本公告发布之日起6个月后受理的新药上市申请适用《E3：临床研究报告的结构与内容》及《E3问答（R1）》。

三、本公告发布之日起3个月后受理的新药上市申请以及6个月后批准的新药上市申请适用《E2E：药物警戒计划》。

四、本公告发布之日起6个月后启动的药物临床研究的相关要求适用《E4：药品注册所需的量效关系信息》《E7：特殊人群的研究：老年医学》及《E7问答》《E8：临床试验的一般考虑》《E9：临床试验的统计学原则》《E10：临床试验中对照组的选择以及相关问题》《E11（R1）：用于儿科人群的医学产品的药物临床研究》《E15：基因组生物标志物、药物基因组学、遗传药理学、基因组数据以及样本编码分类的定义》《E16：与药物或生物制品研发相关的生物标志物：资质提交材料的背景、结构以及格式》。

五、本公告发布之日起6个月后批准的临床试验申请以及3年后受理的新药上市申请适用《E1：人群暴露程度：评估非危及生命性疾病长期治疗药物的临床安全性》。

六、本公告发布之日起6个月后新型抗高血压药物临床研究适用《E12A：新型抗高血压药物的临床评价原则》，其中安全性评估所需受试者样本量要求按照E1实施时间点要求。

相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。

附件（略）。

(2019-11-12)

NMPA Issued the *Announcement on Revising the Package Inserts of Prescription and Over-the-counter Oral Preparations such as Huoxuezhitong Capsules*

In accordance with the results of the Adverse Drug Reaction Evaluation, in order to further ensure the safety of public medication, on November 8, 2019, NMPA issued an Announcement with decisions made to revise the Entries of [warnings], [adverse reactions], [contraindications] and [precautions] of oral preparations (tablets, powders, soft capsules, capsules) such as Huoxuezhitong capsules.

(November 8, 2019)

国家药品监督管理局发布关于修订活血止痛胶囊等口服制剂处方药和非处方药说明书的公告

根据药品不良反应评估结果，为进一步保障公众用药安全，2019年11月8日，国家药品监督管理局发布公告，决定对活血止痛胶囊等口服制剂（片剂、散剂、软胶囊剂、胶囊剂）药品说明书【警示语】【不良反应】【禁忌】和【注意事项】项进行修订。

(2019-11-08)

Medical Devices

NMPA Announcement on the Issuance of Five Guidelines for Technical Review of the Registration of Human Chromosomal Abnormality Detection Reagents Based on Cytofluorometric In Situ Hybridization and Others

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on November 15, 2019 the *Guidelines for Technical Review of the Registration of Human Chromosome Abnormality Detection Reagents Based on Cytofluorometric In Situ Hybridization, Guidelines for Technical Review of the Registration of Multiple Nucleic Acids Detection Reagents for Respiratory Virus, Guidelines for Technical Review of the Registration of Nucleic Acid-Based Detection Reagents for Staphylococcus Aureus and Methicillin-Resistant Staphylococcus Aureus, Guidelines for Technical Review of the Registration of Detection Reagents for Chlamydia Trachomatis and / or Neisseria Gonorrhoeae Nucleic Acids, and Guidelines for Technical Review of the Registration of Amino Acid, Carnitine, and Succinylacetone.*

(November 15, 2019)

医疗器械

国家药品监督管理局发布关于基于细胞荧光原位杂交法的人类染色体异常检测试剂等5项注册技术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《基于细胞荧光原位杂交法的人类染色体异常检测试剂注册技术审查指导原则》《呼吸道病毒多重核酸检测试剂注册技术审查指导原则》《基于核酸检测方法的金黄色葡萄球菌和耐甲氧西林金黄色葡萄球菌检测试剂注册技术审查指导原则》《沙眼衣原体和／或淋病奈瑟菌核酸检测试剂注册技术审查指导原则》和《氨基酸、肉碱及琥珀酰丙酮检测试剂注册技术审查指导原则》，于2019年11月15日发布。

(2019-11-15)

NMPA Announcement on the Issuance of 13 Guidelines for Technical Review of the Registration of Augmented Extremity Compression Therapy Equipment and Others

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on November 15, 2019 the *Guidelines for Technical Review of the Registration of Augmented Extremity Compression Therapy Equipment, Guidelines for Technical Review of the Registration of Medical Device Products Under Benefits-Risk Assessment, Guidelines for Technical Review of the Registration of Direct Ophthalmoscopes, Guidelines for Technical Review of the Registration of Medical Diagnostic X-Ray Tube Assembly, Guidelines for Technical Review of the Registration of Electromyographic Biofeedback Therapy Device, Guidelines for Technical Review of the Registration of Surgery Drills for Dental Implant, Guidelines for Technical Review of the Registration of Artificial Resuscitators, Guidelines for Technical Review of the Registration of Active and Passive Rehabilitation Training Equipment for Upper and Lower Limbs, Guidelines for Technical Review of the Registration of Single-use Endoscopic Biopsy Forceps, Guidelines for Technical Review of the Registration of Plasma Quick Freezer, Guidelines for Technical Review of the Registration of Enteral Feeding Pump, Guidelines for Technical Review of the Registration of Apex Locator, and the Guidelines for Technical Review of the Registration of Urodynamic Analyzer.*

(November 15, 2019)

国家药品监督管理局发布关于肢体加压理疗设备等13项注册技术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《肢体加压理疗设备注册技术审查指导原则》《医疗器械产品受益-风险评估注册技术审查指导原则》《直接检眼镜注册技术审查指导原则》《医用诊断X射线管组件注册技术审查指导原则》《肌电生物反馈治疗仪注册技术审查指导原则》《牙科种植手术用钻注册技术审查指导原则》《人工复苏器注册技术审查指导原则》《上下肢主被动运动康复训练设备注册技术审查指导原则》《一次性使用内镜用活体取样钳注册技术审查指导原则》《血浆速冻机注册技术审查指导原则》《肠内营养泵注册技术审查指导原则》《牙根尖定位仪注册技术审查指导原则》《尿动力学分析仪注册技术审查指导原则》，于2019年11月15日发布。

(2019-11-15)

NMPA *Announcement on the Issuance of 21 Medical Device Industry Standards such as YY / T 0464-2019 Single-Use Hemoperfutor and 1 Modification Order*

On November 13, 2019, NMPA issued the *Announcement on 21 Medical Device Industry Standards such as YY / T 0464-2019 Single-Use Hemoperfutor and 1 Modification Order*. For the codes, names, scope of application and implementation date of the standards, please see the attachment (omitted) .

(November 13, 2019)

国家药品监督管理局发布关于YY/T 0464-2019《一次性使用血液灌流器》等21项医疗器械行业标准和1项修改单的公告

2019年11月13日，国家药品监督管理局发布关于YY/T 0464-2019《一次性使用血液灌流器》等21项医疗器械行业标准和1项修改单的公告，标准编号、名称、适用范围和实施日期等内容见附件（略）。 (2019-11-13)

NMPA Issued Three Guidelines for Technical Review of the Registration of Embryo Replacement Catheter in Assisted Reproduction and Others

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on November 1, 2019 the *Guidelines for Technical Review of the Registration of Embryo Replacement Catheter in Assisted Reproduction, Guidelines for Technical Review of the Registration of Methods for the Determination and Identification of Known Leachables in Medical Devices*, and the *Guidelines for Technical Review of the Registration and Application of Cardiopulmonary Bypass System Extracorporeal Circulation Tubes*.

(November 1, 2019)

国家药品监督管理局发布辅助生殖用胚胎移植导管等3项注册技术审查指导原则

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《辅助生殖用胚胎移植导管注册技术审查指导原则》《医疗器械已知可沥滤物测定方法验证及确认注册技术审查指导原则》《心肺转流系统体外循环管道注册申报技术审查指导原则》，于2019年11月1日发布。 (2019-11-01)

NMPA Issued Four *Guidelines for Technical Review of the Registration of Assay Reagents for Aspartate Aminotransferase* and Others

To strengthen the supervision and guidance over medical device product registration and further improve the quality of registration review, NMPA has organized the formulation of and released on October 29, 2019 the *Guidelines for Technical Review of the Registration of Assay Reagents for Aspartate Aminotransferase, Guidelines for Technical Review of the Registration of Total Cholesterol Assay Reagents, Guidelines for the Technical Review of Registration of Uric Acid Determination Reagents*, and *Guidelines for Technical Review of the Registration of Urea Determination Reagents.*

(October 29, 2019)

国家药品监督管理局发布天门冬氨酸氨基转移酶测定试剂等4项注册技术审查指导原则

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《天门冬氨酸氨基转移酶测定试剂注册技术审查指导原则》《总胆固醇测定试剂注册技术审查指导原则》《尿酸测定试剂注册技术审查指导原则》和《尿素测定试剂注册技术审查指导原则》，于2019年10月29日发布。 (2019-10-29)

Annual Report

Release of *Annual Report for National Medical Device Adverse Event Monitoring (2018)*

To fully reflect the monitoring of adverse events in China's medical devices in 2018, the National Center for Adverse Drug Reaction Monitoring has compiled and released on October 30, 2019 the *Annual Report for National Medical Device Adverse Event Monitoring (2018)*, which is excerpted as follows:

年报

《国家医疗器械不良事件监测年度报告（2018年）》发布

为全面反映2018年我国医疗器械不良事件监测情况，国家药品不良反应监测中心编撰了《国家医疗器械不良事件监测年度报告（2018年）》，于2019年10月30日发布。部

I. Progress of medical device adverse events monitoring

In 2018, with the pioneering efforts of our staff, the national medical device adverse event monitoring has continued to advance, the monitoring scope continued to expand, the report collection capability was significantly improved, and the number of reports saw a persistent increase. The ability of monitoring personnel to analyze and evaluate adverse events has been continuously improved to effectively detect and deal with risks, the principal responsibility of manufacturers' monitoring of adverse events has been gradually implemented, and new progress has been made in this field.

(I) The construction of monitoring information system has been promoted, and network coverage has been expanded to improve data quality

In 2018, the Information System for National Medical Device Adverse Event Monitoring has received more than 400,000 Reports for Suspected Adverse Events of Medical Devices, and the quality of the reports was improved. There are more than 270,000 registered users at the grassroots level of the system, of which more than 13,000 are manufacturers, an increase of 16.44% over last year. 95.9% of districts and counties across China reported medical device adverse events, with an average of 305 reports per million people. In addition, the National Center for Adverse Drug Reaction Monitoring completed the establishment of a new information system for monitoring adverse events in medical devices, realizing the replacement of the online reporting system for such events in China, provide strong support for the implementation of the *Administrative Measures for Monitoring and Re-evaluating the Adverse Events of Medical Devices* (hereinafter referred to as the *Measures*) .

(II) The analysis and evaluation of monitoring data are reinforced for product risks mining and promoting the safety of medical devices.

In 2018, the evaluation and disposal of risk signals for the monitoring of adverse events in medical devices were carried out in depth. We've strengthened the daily monitoring, early warning analysis and quarterly summary of national medical device adverse event reports. Based on the risk conditions, 3 issues of *Medical Device Adverse Event Information Notification and 6 Medical Device Pharmacovigilance Expresses* were issued throughout the year. The intensive monitoring of adverse events in medical devices *13th Five-Year Plan* continued to advance. The National Center for ADR Monitoring has organized inspections on key surveillance work. The relevant undertaking units proactively collected monitoring data to dig deeper into the risks of medical devices, and the relevant work saw steady progress.

(III) We carried out technical training on monitoring regulations, and actively participated in international exchanges to improve the level of the monitoring teams

To support the implementation of the newly revised *Measures*, the National Adverse Drug Reaction Monitoring Center trained a total of 393 monitoring institutions throughout the year, achieving full coverage of training at provincial-level monitoring institutions. Supervision departments at all levels have organized special training courses on the *Measures* and related guiding principles to improve the ability of monitoring personnel and reinforce the principal responsibility of production enterprises. In addition, we actively followed up the progress of adverse event terminology in IMDRF (International Medical Device Regulators Forum) and promoted China's participation in the National Competent Authority Report (NCAR) System, which further enhanced the level of internationalization.

II. General situation of medical device adverse event reporting

(I) Overview of reporting in 2018

1.Number of Medical Device Adverse Event Reports in China

In 2018, the National Medical Device Adverse Event Monitoring Information System received a total of 406,974 reports

分内容如下：

一、医疗器械不良事件监测工作进展

2018年，在全国医疗器械不良事件监测工作人员的开拓努力下，全国医疗器械不良事件监测工作持续推进，监测范围不断扩大，报告收集能力明显提升，报告数量继续增加。监测人员不良事件分析评价能力不断提高，有效提高了风险的发现和处置能力，生产企业不良事件监测主体责任逐步得到落实，医疗器械不良事件监测工作取得了新的进展。

（一）推进监测信息系统建设，扩大网络覆盖提升数据质量

2018年，全国医疗器械不良事件监测信息系统接收可疑医疗器械不良事件报告40余万份，报告质量得到提高。系统基层注册用户达到27万余家，其中生产企业1.3万余家，较去年增长16.44%。全国95.9%的区县报告了医疗器械不良事件，每百万人口平均报告数为305份。此外，国家药品不良反应监测中心完成医疗器械不良事件监测新信息系统的搭建测试，实现了我国医疗器械不良事件在线报告系统的新旧更替，为《医疗器械不良事件监测和再评价管理办法》（以下简称《办法》）的贯彻落实提供有力支撑。

（二）夯实监测数据分析评价，挖掘产品风险促进用械安全

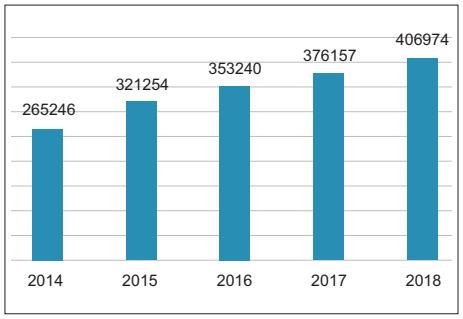
2018年，医疗器械不良事件监测风险信号评价处置工作深入开展。强化对全国医疗器械不良事件报告的日常监测、预警分析及季度汇总，根据发现的风险情况，全年共发布《医疗器械不良事件信息通报》3期、《医疗器械警戒快讯》6期。“十三五”医疗器械不良事件重点监测工作持续推进。国家药品不良反应监测中心组织对重点监测工作进行督查，相关承担单位主动收集监测数据，深入挖掘医疗器械风险，工作进展顺利。

（三）开展监测法规技术培训、积极参与国际交流，提升监测队伍水平

为配合新版《办法》的实施，国家药品不良反应监测中心全年共培训监测机构393人次，实现了对省级监测机构培训的全覆盖。各级监管部门组织开展了《办法》及相关指导原则的专项培训班，提升监测人员能力水平，强化生产企业主体责任。此外，积极跟进国际医疗器械监管机构论坛不良事件术语工作进展，推动我国加入国际医疗器械监管机构报告工作机制 (NCAR)，国际化水平进一步提升。

of suspected medical device adverse events, an increase of 8.19% over 2017, reflecting the increasing awareness of China's medical device adverse event reporting and the effective enhancement of report collection capabilities (Figure 1) .

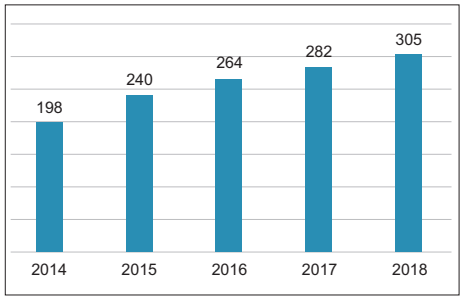
图1 2014年至2018年全国可疑医疗器械不良事件报告数量
Figure 1. Number of Suspected Medical Device Adverse Events Reported from 2014 to 2018



2. Average number of reports per million population

In 2018, the average number of suspected medical device adverse events reported per million people in China was 305, an increase of 23 compared with 2017 (Figure 2)

图2 2014年至2018年全国百万人口平均可疑医疗器械不良事件报告数比较
Figure 2 Comparison of the number of suspected medical device adverse events reported per million people across China from 2014 to 2018



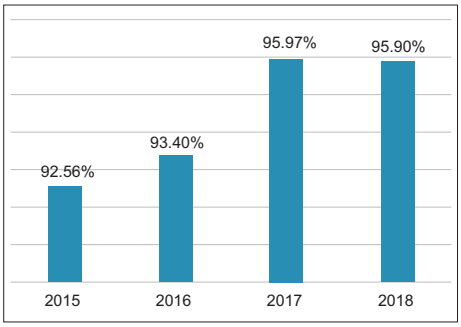
3. County-level coverage

In 2018, the county-level coverage of suspected medical device adverse events in China was 95.9% (Figure 3) .

(II) Number of registered grassroots users nationwide

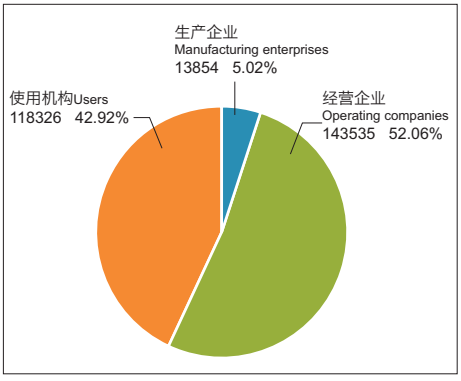
As of December 31, 2018, there were a total of 275,715 grassroots user units (including manufacturing enterprises, operating companies and users) registered in the National Medical Device Adverse Event

图3 2015年至2018年全国可疑医疗器械不良事件报告县级覆盖率
Figure 3 County-level coverage of suspected medical device adverse event reports from 2015 to 2018 in China



Monitoring Information System, cover 13,854 manufacturers (5.02%); 143,535 distributors (52.06%); 118,326 user units (42.92%) (Figure 4) .

图4 2018年年全国医疗器械不良事件监测信息系统注册基层用户情况
Figure 4 Status of registered grassroots users in the National Medical Device Adverse Event Monitoring Information System in 2018



In 2018, the total number of registered grassroots users increased by 8.87% over 2017. It shows that the scope of monitoring of adverse events of medical devices in China has been expanding. Among them, the registered grassroots users of manufacturers, distributors and user units have increased by 16.44%, 11.59% and 4.97% over 2017, respectively (Figure 5) .

III. Statistical analysis of national medical device adverse event reports (omitted)

IV. Release of medical device adverse event information notification (omitted)

V. Issuance of Pharmacovigilance Expresses on Medical Devices (omitted)

VI. Explanation of relevant information (omitted)

(October 30, 2019)

二、全国医疗器械不良事件报告总体情况

（一）2018年度报告总体情况

1. 全国医疗器械不良事件报告数量

2018年，全国医疗器械不良事件监测信息系统共收到可疑医疗器械不良事件报告406974份，较2017年增长8.19%，反映出我国医疗器械不良事件报告意识不断增强、报告收集能力有效提升（图1）。

2. 每百万人口平均报告数量

2018年，我国每百万人口平均可疑医疗器械不良事件报告数为305份，与2017年相比增长23份（图2）

3. 县级覆盖率

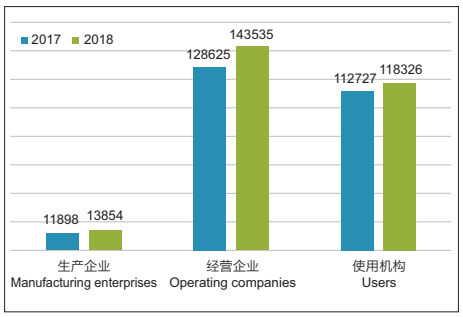
2018年，我国可疑医疗器械不良事件报告的县级覆盖率为95.9%（图3）。

（二）全国注册基层用户数量

截至2018年12月31日，在全国医疗器械不良事件监测信息系统注册的基层用户（包括生产企业、经营企业和使用单位）共275715家，其中生产企业13854家，占注册基层用户总数的5.02%；经营企业143535家，占注册基层用户的52.06%；使用单位118326家，占注册基层用户的42.92%（图4）。

2018年，注册基层用户总数比2017年增长8.87%。显示我国医疗器械不良事件监测范围不断扩大。其中生产企业、经营企业和使用单位的注册基层用户分别比2017年增长16.44%、11.59%和4.97%（图5）。

图5 2017年、2018年年全国注册基层用户分类比较情况
Figure 5 Classified comparison of national registered grassroots users in 2017 and 2018



三、全国医疗器械不良事件报告统计分析（略）

四、医疗器械不良事件信息通报发布情况（略）

五、医疗器械警戒快讯发布情况（略）

六、有关情况说明（略）

(2019-10-30)

Notes:
- All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
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