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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

2019 *National Safe Medication Month Activity* Launched in Beijing

On October 17, 2019, the Launching Ceremony for 2019 *National Safe Medication Month* Activity and the 4th China Drug Safety Forum hosted by NMPA and jointly undertaken by China Pharmaceutical Association and People's Daily Online (People's Health Section) were held in Beijing. NMPA Commissioner Jiao Hong attended the launching ceremony and delivered a speech.

With the CPC Central Committee and the State Council attaching great importance to safety medication for the people, China's drug administration laws and regulations have gradually developed and improved, providing effectively a solid guarantee for the sustainable development of China's pharmaceutical industry and the people's safe use of drugs. In 2019, China's drug administration has achieved new results and reached a new level. Significant progress has been made in the construction of the regulatory system: The *Vaccine Administration Law* and the newly revised *Drug Administration Law* have been promulgated successively; the amendments to the *Regulations for the Supervision and Administration of Medical Devices*, and the *Regulations for the Supervision and Administration of Cosmetics* are also to be submitted to the State Council executive meeting for deliberation. The reform of the review & approval system continued to deepen: Since the beginning of this year, 331 applications for drug registration have been approved, covering 11 new overseas drugs catering to urgent clinical needs; the consistency evaluation of the quality and efficacy of generic drugs have been completed for 110 varieties and 277 specifications; 658 applications for medical device registration have been approved, covering 14 innovative medical devices, and online electronic application has been achieved for medical device registration; cosmetics registration record-filing management has been improved, registration renewal for special-purpose cosmetics has been adjusted to the Informing & Pledging System for examination and approval, cutting the time cycle for corporate business process from 115 to 15 working days. The supervision of the whole life cycle of drugs has been continuously reinforced, the foundation of scientific supervision has gradually consolidated, and international cooperation has been beefed up.

This year's Activity of National Safe Medication Month is based on the theme of *Safe Medication*, *Good Law and Good Governance*. Good law forms the basis of good governance, which is the goal of good law.

As an important means of popularizing science and technology for drug safety, this Activity has been held for 12 consecutive years since 2007, and has played an important role in popularizing drug safety knowledge and promoting social co-governance. During the event, drug regulatory authorities at all levels will organize various forms of publicity activities, encompassing public open days, online knowledge competitions, interactive experience workshops, etc., which jointly promote exchanges, enhance public scientific literacy, and promote social co-governance in the field of drug safety.

(October 17, 2019)

2019年全国安全用药月活动在京启动

2019年10月17日，由国家药品监督管理局主办，中国药学会、人民网·人民健康承办的2019年全国安全用药月启动仪式暨第四届中国药品安全论坛在京举办。国家药品监督管理局局长焦红出席启动仪式并致辞。

党中央、国务院高度重视药品安全工作，我国药品法律法规逐渐发展完善，为我国药品事业持续发展、人民用药安全有效提供了坚实保障。2019年，药品监管工作取得新成效、迈上新台阶。法规体系建设取得重大进展：《疫苗管理法》和新修订《药品管理法》先后出台；《医疗器械监督管理条例》修正案和《化妆品监督管理条例》也即将提请国务院常务会议审议。审评审批制度改革持续深化：今年以来，批准药品注册申请331件，其中临床急需境外新药11个；110个品种277个品规完成仿制药质量和疗效一致性评价；批准医疗器械注册申请658件，创新医疗器械14个，医疗器械注册实现网上电子申报；完善化妆品注册备案管理，特殊用途化妆品延续许可调整为承诺制审批，企业办事流程由115个工作日压缩至15个工作日。药品全生命周期监管不断加强，科学监管基础逐步夯实，国际合作力度加大。

今年全国安全用药月活动以“安全用药 良法善治”为主题。良法是善治的开始，善治是良法的目标。

全国安全用药月活动是药品安全科普宣传的重要手段，自2007年起已连续举办12届，为普及药品安全知识，推进社会共治发挥了重要作用。活动期间，各级药品监管部门将组织形式多样的宣传活动，包括公众开放日、网络知识竞赛、互动体验活动等，共同促进药品安全领域交流、提升公众药品安全科学素养、推动药品安全社会共治。

(2019-10-17)

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NMPA Issued the *Announcement on Registration Application Situation and Self-Examination & Verification of Drug Clinical Trial Data*

On October 15, 2019, NMPA released the *Announcement on Registration Application Situation and Self-Examination & Verification of Drug Clinical Trial Data* with decision made to verify the clinical trial data of 7 newly received registration applications for drugs that have completed the clinical trials and are applying for production, the relevant issues are hereby announced:

I. If the drug registration applicants found inauthenticity of clinical trial data by self-examination before NMPA verification, they shall take the initiative to apply for withdrawal of registration application, NMPA shall announce the list of applicants and varieties withdrawn without affixing accountability.

II. NMPA Center for Food and Drug Inspection shall publicize on its website and inform the applicants of drug registration and the competent local provincial drug regulatory authority of the on-site verification plan. The Center shall, 10 working days after the public notification, inform the date for on-site verification and no longer accept the applicants' withdrawal of drug registration applications.

III. Pursuant to the law, NMPA shall severely punish the applicants, responsible persons and managers of drug clinical trials and responsible persons of CROs found with data frauds in drug clinical trial data on-site verification.

Annex: List of Registration Applications for 7 Drugs with Self-Examination & Verification of Clinical Trial Data (Omitted)

(October 15, 2019)

国家药品监督管理局发布关于药物临床试验数据自查核查注册申请情况的公告

2019年10月15日，国家药品监督管理局发布关于药物临床试验数据自查核查注册申请情况的公告，决定对新收到的7个已完成临床试验申报生产的药品注册申请进行临床试验数据核查，并将有关事宜公告如下：

一、在国家药品监督管理局组织核查前，药品注册申请人自查发现药物临床试验数据存在真实性问题的，应主动撤回注册申请，国家药品监督管理局公布其名单，不追究其责任。

二、国家药品监督管理局食品药品审核查验中心将在其网站公示现场核查计划，并通知药品注册申请人及其所在地省级药品监管部门，公示10个工作日后，该中心将通知现场核查日期，不再接受药品注册申请人的撤回申请。

三、对药物临床试验数据现场核查中发现数据造假的申请人、药物临床试验责任人和管理人、合同研究组织责任人，国家药品监督管理局将依法严肃处理。

附件：7个药物临床试验数据自查核查注册申请清单（略）　　(2019-10-15)

NMPA Issued the *Technical Guidelines for Endpoints in Clinical Trials for Advanced Non-Small Cell Lung Cancer*

To standardize and guide the clinical trial design and endpoint selection of drugs for the treatment of advanced non-small cell lung cancer in China, and provide referable technical specifications, NMPA has organized the formulation of and released on September 18, 2019 the *Technical Guidelines for Endpoints in Clinical Trials for Advanced Non-Small Cell Lung Cancer.*

(September 18, 2019)

国家药品监督管理局发布《晚期非小细胞肺癌临床试验终点技术指导原则》

为规范和指导我国治疗晚期非小细胞肺癌药物的临床试验设计和终点选择，提供可参考的技术规范，国家药品监督管理局组织制定了《晚期非小细胞肺癌临床试验终点技术指导原则》，于2019年9月18日发布。

(2019-09-18)

Medical Devices

NMPA Issued the *Announcement on Effective Implementation of Unique Identification for the First Batch of Medical Devices*

The *Rules for Unique Identification System for Medical Devices* (hereinafter referred to as the Rules), released in August 2019, has ushered in the stepwise implementation of Unique Identification system for medical devices. On October 14, 2019, NMPA issued the *Announcement on Effective Implementation of Unique*

医疗器械

国家药品监督管理局发布《关于做好第一批实施医疗器械唯一标识工作有关事项的通告》

《医疗器械唯一标识系统规则》（以下简称《规则》）已于2019年8月发布。按照《规则》要求，分步推行医疗器械唯一标识制度。2019年10月14日，国家药品监督管

Identification for the First Batch of Medical Devices (hereinafter referred to as the Announcement), which clearly defines the scope, schedule and work requirements of unique identification for the first batch of medical devices. According to the *Announcement*, from October 1, 2020, the medical devices listed in the first batch for implementation should have the unique identification.

As per the degree of risk and regulatory needs, the *Announcement* identifies some high-risk Class III medical devices such as active/passive implants into the first batch. Nine categories and 64 varieties, say cardiac pacemakers, hip prostheses, and plastic injection fillers, etc., were also enlisted in the first product catalogue for the first batch.

As per the *Announcement*, for medical devices listed in the first batch, the registrant shall follow the Rules, timely, orderly and effectively perform the coding of Unique Identification, and complete the submission of the registration system and database for unique identification. As per the *Announcement*, unique identification is optional prior to October 1, 2020, but mandatory for all medical devices produced thenceforward (judged by the date of manufacture on the tags of medical devices).

The *Announcement* requires that, as from October 1, 2020, when applying for initial registration, registration renewal or alterations, the registered applicant/registrant shall submit the product identification of the smallest sales unit in the registration management system. The product identification does not constitute a registration review item, therefore its individual change of identification does not belong to the category of registration alterations.

The *Announcement* further states that, before the sale of medical devices produced since October 1, 2020, the registrant shall, in accordance with the relevant standards or specifications, upload the product identification and related data of the minimum sales unit and higher-level packaging to the unique identification database of medical devices; and ensure data alteration and update where any data-related changes arise. When the product identification of the minimum sales unit of the medical device changes, the data should be uploaded to the unique identification database per the *newly added product identification*.

The *Announcement* also requires that the registrants for the first batch shall strictly follow the requirements to organize the coding, data uploading and maintenance, and shall be responsible for the authenticity, accuracy and completeness of the data. Registrants are encouraged to apply medical device unique identification to establish medical device information-based traceability system, to realize traceability of the whole process of production, circulation and use of the products. Medical device manufacturers and distributors and users are encouraged to actively apply the unique identification of medical devices in their relevant management activities, and explores the establishment of upstream and downstream traceability chain, to promote the convergence of applications. Relevant departments shall actively carry out training and publicity. (October 15, 2019)

理局印发了《关于做好第一批实施医疗器械唯一标识工作有关事项的通告》（以下简称《通告》）。

《通告》对第一批医疗器械唯一标识实施品种范围、进度安排、工作要求等进行了明确规定。根据《通告》，2020年10月1日起，生产列入首批实施目录的医疗器械，应当具有医疗器械唯一标识。

按照风险程度和监管需要，《通告》确定部分有源植入类、无源植入类等高风险第三类医疗器械作为第一批医疗器械唯一标识实施品种。心脏起搏器、髋关节假体、整形用注射填充物等九大类64个品种被列入第一批实施医疗器械唯一标识的产品目录。

《通告》要求，对列入首批实施目录的医疗器械，注册人应当遵循《规则》要求，按时限有序做好唯一标识赋码、完成唯一标识注册系统提交以及完成唯一标识数据库提交等相关工作。根据《通告》，2020年10月1日起，生产的医疗器械应当具有医疗器械唯一标识；2020年10月1日前已生产的医疗器械可不具有医疗器械唯一标识。生产日期以医疗器械标签为准。

《通告》要求，2020年10月1日起，申请首次注册、延续注册或者注册变更时，注册申请人/注册人应当在注册管理系统中提交其最小销售单元的产品标识。产品标识不属于注册审查事项，产品标识的单独变化不属于注册变更范畴。

此外，根据《通告》，2020年10月1日起生产的医疗器械，在其上市销售前，注册人应当按照相关标准或者规范要求将最小销售单元、更高级别包装的产品标识和相关数据上传至医疗器械唯一标识数据库；当医疗器械产品最小销售单元产品标识的相关数据发生变化时，注册人应当在该产品上市销售前，在医疗器械唯一标识数据库中进行变更，实现数据更新。医疗器械最小销售单元产品标识变化时，应当按照新增产品标识上传数据至医疗器械唯一标识数据库。

《通告》同时要求，第一批实施唯一标识工作的注册人严格按照要求组织开展赋码、数据上传和维护等工作，并对数据真实性、准确性、完整性负责；鼓励注册人应用医疗器械唯一标识建立医疗器械信息化追溯系统，实现对其产品生产、流通、使用全程可追溯；鼓励医疗器械生产经营企业、使用单位在其相关管理活动中积极应用医疗器械唯一标识，探索建立与上下游的追溯链条，推动衔接应用；相关部门积极开展培训宣传。

（2019-10-15）

NMPA Issued Guidelines for Technical Review of the Registration of Custom-Made and Material Additive-Based Medical Devices of Passive Implantable Bones, Joints and Oral Hard Tissues

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration examination, NMPA has organized the formulation of and released on May 15, 2019 the *Guidelines for Technical Review of the Registration of Custom-Made and Material Additive-Based Medical Devices of Passive Implantable Bones, Joints and Oral Hard Tissues.*

(October 15, 2019)

国家药品监督管理局发布无源植入性骨、关节及口腔硬组织个性化增材制造医疗器械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《无源植入性骨、关节及口腔硬组织个性化增材制造医疗器械注册技术审查指导原则》，于2019年10月15日发布。 (2019-10-15)

Annual Report

NMPA issued the *Announcement on the Annual Report for National ADR Monitoring (2018)*

On October 18, 2019, NMPA issued the *Announcement on the Annual Report for National ADR Monitoring (2018)*, which is excerpted as follows:

I. Overall Situation of Adverse Drug Reaction Monitoring

From 1998 to 2018, China's national ADR Monitoring has gone through the vicissitudes of two decades, during which NMPA focused on building an ADR monitoring system, improving relevant laws and regulations, expanding monitoring coverage, and establishing an early warning mechanism based on risk prevention and control. ADR monitoring has thus developed rapidly. In 2018, in accordance with the *Four Strictest (Strictest Standards, Regulation, Punishment, and Accountability)* requirements put forward by General Secretary Xi Jinping on food and drug safety, adhering to the motif of safeguarding the safety of the people's medication, new progresses have been made in ADR Monitoring:

First, reinforce *intelligent supervision* and further expand the coverage of monitoring. We've ameliorated the national ADR monitoring network system, developed and constructed the monitoring system wherein the Marketing Authorization Holders shall directly report the ADR, and expanded the monitoring coverage. In 2018, 97.9% of the districts and counties reported ADRs, and the national average number of reports per million population reached 1,119, which has achieved the corresponding goal in the 13th Five-Year Plan. We continued to expand our monitoring techniques & approaches and cooperated with medical institutions to build more than 150 monitoring sentinels, providing a solid foundation for monitoring.

Second, conduct in-depth safety evaluation and timely address risk warning signals. Based on monitoring data analysis and evaluation results, in 2018, we've released a total of 33 Announcements on the revision of drug package inserts; mandated the cessation of production, sales and use of Pyrithioxine Injections, Composite Terfenadine Tablets, Sulfisomidiae Tablets and Terfenadine, Ibuprofen and Pseudoephedrine Capsules, and issued 12 volumes of *Pharmacovigilance Express*. We continued to optimize the early warning system and timely handled more than 150 highly concerned ADR-events clustering signals, focusing on early detection, early response, early investigation and early disposal to ensure safety of public drug use.

Third, reinforce the principal responsibility of Marketing Authorization Holders (MAHs) for drug safety. In September 2018, NMPA issued the *Announcement on the Direct Reporting of Adverse Reactions by Marketing Authorization Holders* (Announcement No. 66 of 2018) and the

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《国家药品不良反应监测年度报告(2018年)》发布

2019年10月18日，国家药品监督管理局发布《国家药品不良反应监测年度报告（2018年）的通告》，部分内容如下：

一、药品不良反应监测工作情况

从1998年到2018年，国家药品不良反应监测工作已走过20年历程。在此期间，国家药品监督管理局着力构建药品不良反应监测体系、完善相关法律法规、扩大监测覆盖面、建立以风险防控为主的预警机制，不良反应监测工作得到快速发展。2018年，按照习近平总书记对食品药品安全提出的“四个最严”要求，秉承保障人民群众用药安全的主旨，药品不良反应监测工作取得新进展:

一是强化智慧监管，监测覆盖面进一步扩大。完善国家药品不良反应监测网络系统,开发建设持有人直接报告药品不良反应监测系统，监测覆盖面不断增大。2018年全国97.9%的区县报告了药品不良反应，每百万人口平均报告数为1119份，已实现“十三五”规划目标。继续拓展监测技术手段，与医疗机构合作建设了150余家监测哨点，为监测工作深入开展夯实基础。

二是深入开展安全性评价，及时处置风险预警信号。根据监测数据分析评价结果，2018年共发布药品说明书修订公告33期、停止吡硫醇注射剂、特酚伪麻片、磺胺索嘧啶片和特洛伪麻胶囊生产销售使用、发布《药物警戒快讯》12期。继续优化预警系统，对重点关注的150余个药品不良反应事件聚集性信号及时进行处置，做到早发现、早应对、早调查、早处置，保障公众用药安全。

Announcement on the Issuance of the Guidelines for the Collection and Reporting of Adverse Drug Reactions in Individual Cases (No. 131 of 2018), further reinforced the responsibility of MAHs for drug safety, and put forward specific requirements for monitoring, reporting, analysis and evaluation of the MAHs.

II. ADR/ADE (adverse drug event) reporting

(A) Overview of reporting

1. 2018 Annual ADR/ADE Reporting

In 2018, the National ADR Monitoring Network received 1.499 million copies of the Report on Adverse Drug Reactions/ Events. From 1999 to 2018, the National ADR Monitoring Network received a total of 13.68 million copies of the *ADRs / ADEs Report Forms* (Figure 1).

2. New and Serious ADR/ADE Reporting

In 2018, the National ADR Monitoring Network received 495,000 new and serious ADR/ADE reports, accounting for 33.1% of the total number reported in the same period. The steady growth of the proportion of new and serious ADR/ADE reports indicates a constant upclimbing of the availability of ADR reports in China.

In 2018, the National ADR Monitoring Network received 149,000 reports of serious ADRs/ADEs, accounting for 10.0% of the total number of reports in the same period

图1. 1999年2018年全国药品不良反应/事件报告数量增长趋势
Figure 1 1999-2018 growth trend of ADR/ADE reports in China

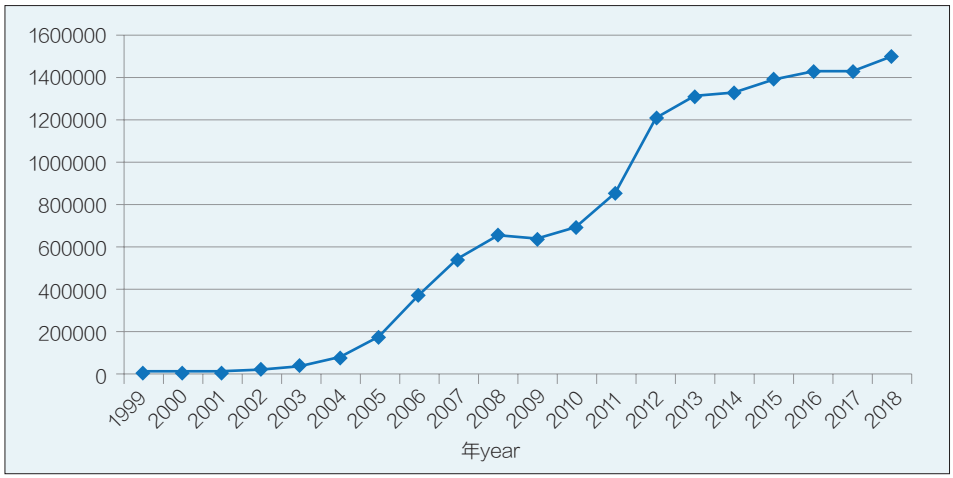
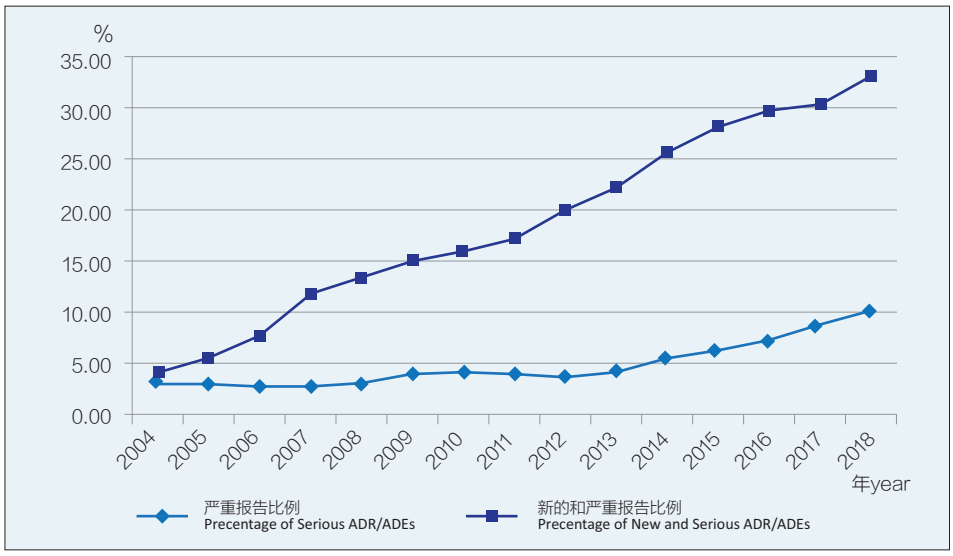


图2. 2004年—2018年新的和严重以及严重药品不良反应/事件报告比例
Figure 2 Precentage of 2004-2018 New and Serious ADR/ADE as well as Serious ADR/ADE Reporting



三是夯实上市许可持有人药品安全主体责任。2018年9月，国家药品监督管理局发布《关于药品上市许可持有人直接报告不良反应事宜的公告》（2018年第66号）和《关于发布个例药品不良反应收集和报告指导原则的通告》（2018年第131号），进一步强化上市许可持有人药品安全主体责任，对上市许可持有人开展监测、报告、分析和评价提出具体要求。

二、药品不良反应/事件报告情况

(一) 报告总体情况

1. 2018年度药品不良反应/事件报告情况

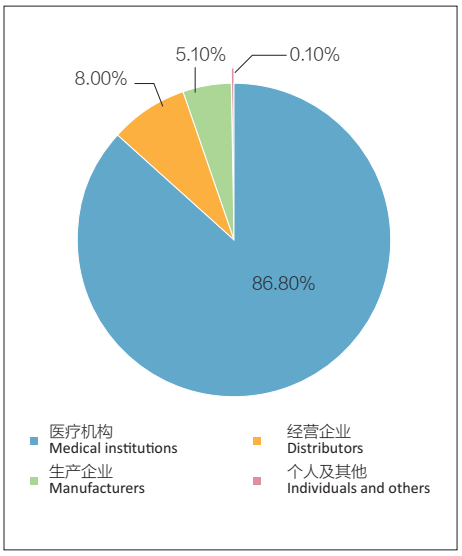
2018年全国药品不良反应监测网络收到《药品不良反应/事件报告表》149.9万份。1999年至2018年，全国药品不良反应监测网络累计收到《药品不良反应/事件报告表》1368万份（图1）。

2. 新的和严重药品不良反应/事件报告情况

2018年全国药品不良反应监测网络收到新的和严重药品不良反应/事件报告49.5万份；新的和严重药品不良反应/事件报告占同期报告总数的33.1%。新的和严重药品不良反应/事件报告比例持续增加，显示我国药品不良反应报告可利用性持续增加。

2018年全国药品不良反应监测网络收到严重药品不良反应/事件报告14.9万份，严重药品不良反应/事件报告占同期报告总数的10.0%（图2）。

图3. 2018年药品不良反应/事件报告来源分布
Figure 3 Source distribution of ADR/ADE reports in 2018



(Figure 2).

3. Average case report per million population

As one of the important indicators to measure the level of national ADR monitoring, the average number of reports per million people in China marked 1,119 in 2018.

4. ADR/ADE county reporting ratio

ADR/ADE county reporting ratio marks an important indicator for measuring the balanced development and coverage of ADR monitoring in China. The proportion of county-level reports of ADRs/ADEs in China in 2018 was 97.9%.

5. Source of ADR/ADE Reporting

Pharmaceutical manufacturers, distributors and medical institutions constitute the responsible organizations for ADR/ADE reporting. As per source-specific statistics of ADR/ADE reports in 2018, a lion's share of 86.8% came from medical institutions; while a share of 8.0%, 5.1%, and 0.1% came from pharmaceutical distributors, manufacturers, individuals and other sources, respectively (Figure 3).

6. Occupations of reporters

In occupation-specific statistics, doctors accounted for 55.2%, pharmacists accounted for 23.0%, nurses accounted for 15.3%, and other occupations accounted for 6.5% (Figure 4).

7. Patients involved in the ADR/ADE reports

In the 2018 ADR/ADE reports, the ratio of male to female patients was 0.86:1, with men slightly outnumbered by women. Reports of pediatric patients under 14 years of age accounted for 9.8%; reports of elderly patients over the age of 65 accounted for 27.7% (Figure 5).

8. Distribution of drug categories involved in ADR/ADE reports

According to category-specific statistics of suspected drugs, reports of chemical drugs, TCM and bio-products accounted for 83.9%, 14.6% and 1.5%, respectively (Figure 6).

As per the statistics of routes of administration of drugs involved in 2018 ADR/ADE reports, 60.0% were administered by intravenous injection,

图4. 报告人职业构成
Figure 4 Occupational structure of reporters

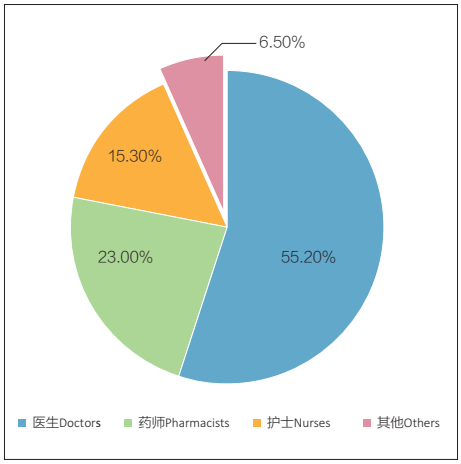


图5. 药品不良反应/事件报告涉及患者年龄分布
Figure 5 Age distribution of patients involved in ADR/ADE reports

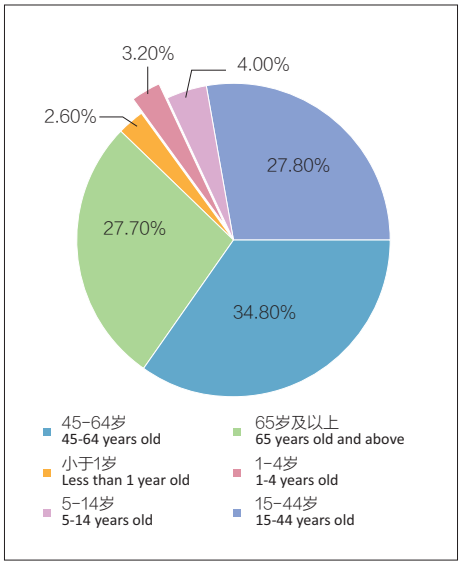
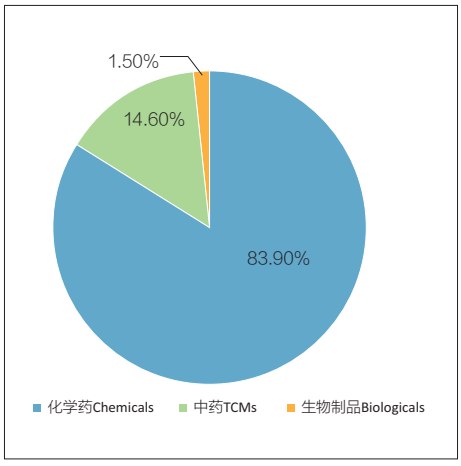


图6. 药品不良反应/事件报告涉及药品类别
Figure 6 Distribution of drug categories involved in ADR/ADE reports



3. 每百万人口平均报告情况

每百万人口平均报告数量是衡量一个国家药品不良反应监测工作水平的重要指标之一。2018年我国每百万人口平均报告数为1119份。

4. 药品不良反应/事件县级报告比例

药品不良反应/事件县级报告比例是衡量我国药品不良反应监测工作均衡发展及覆盖程度的重要指标之一。2018年全国药品不良反应/事件县级报告比例为97.9%。

5. 药品不良反应/事件报告来源

药品生产企业、经营企业和医疗机构是药品不良反应报告的责任单位。按照报告来源统计，2018年来自医疗机构的报告占86.8%；来自药品经营企业的报告占8.0%；来自药品生产企业的报告占5.1%；来自个人及其他报告者的报告占0.1%（图3）。

6. 报告人职业

按照报告人职业统计，医生占55.2%，药师占23.0%，护士占15.3%，其他职业占6.5%（图4）。

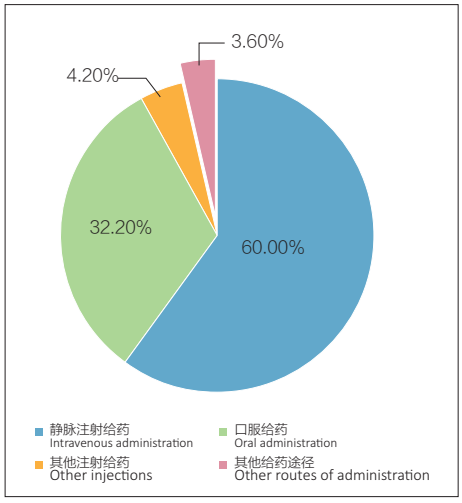
7. 药品不良反应/事件报告涉及患者情况

2018年药品不良反应/事件报告中，男女患者比为0.86：1，女性略多于男性。14岁以下儿童患者的报告占9.8%；65岁以上老年患者的报告占27.7%（图5）。

8. 药品不良反应/事件报告涉及药品情况

按照怀疑药品类别统计，化学药品占83.9%、中药占14.6%、生物制品占1.5%（图6）。

图7. 药品不良反应/事件报告给药途径
Figure 7 Distribution of routes of administration in ADR/ADE reports



4.2% by other injections, 32.2% by oral administration, and 3.6% by other routes of administration (Figure 7).

9. Organ system damaged by ADRs / ADEs

Among the ADRs/ADEs reported in 2018, the top 5 damaged organ systems are: skin and its appendages; gastrointestinal system damage; systemic damage, neurological impairment and cardiovascular system damage (Figure 8).

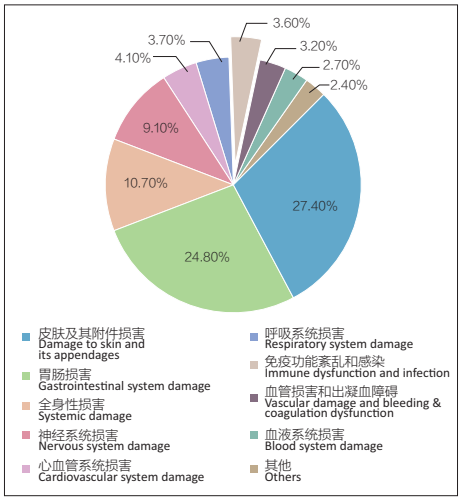
III. Relevant Risks Contrl Meathods (Omitted)

IV. Morograph (Omitted)

V. Relevant Illustration (Omitted)

(October 18, 2019)

图8. 药品不良反应/事件累及器官系统
Figure 8 Organ systems damaged by ADRs / ADEs



按照药品给药途径统计，2018年药品不良反应/事件报告中，静脉注射给药占60.0%、其他注射给药占4.2%、口服给药占32.2%、其他给药途径占3.6%（图7）。

9. 药品不良反应/事件累及器官系统情况

2018年报告的药品不良反应/事件中，累及器官系统排名前5位的分别为皮肤及其附件损害、胃肠损害、全身性损害、神经系统损害和心血管系统损害（图8）。

三、相关风险控制措施（略）

四、各论（略）

五、有关说明 （略）

（2019-10-18）

News Information

2019 ISPE-CCFDIE China Conference held in Nanchang

From October 11 to 13, 2019, the 2019 ISPE-CCFDIE China Conference, jointly organized by China Center for Food and Drug International Exchange (CCFDIE), NMPA Center for Food and Drug Inspection and the International Society for Pharmaceutical Engineering (ISPE), was successfully held in Nanchang. Since its inception in 2007, ISPE-CCFDIE China Conference has been successfully held for 13 consecutive years with various forms and rich contents, and ever-growing authority and influence. The Conference has become an important platform for publicizing China's drug regulatory laws and regulations, understanding the latest regulatory trends overseas, sharing the latest pharmaceutical technologies, and transmitting information. It also plays a positive role in promoting the development of China's pharmaceutical industry, and ensuring the quality and safety of pharmaceutical production.

In 2019, ISPE-CCFDIE China Conference consisted of six special sessions, namely: The Pharmaceutical Production and Quality Management Exchange Conference, the General Assembly, the National Drug Inspection Special Work Conference, the CFDI (Center for Food and Drug Inspection) Special Session, the ICH Q5 Special Session, and the ICH Q6 Special Session; and six Technical Sub-Conferences. The Conference invited more than 60 experts and scholars from the Chinese and foreign drug regulatory authorities, industry associations, and pharmaceutical companies to exchange and discuss hot topics such as the new requirements for production and quality management as per the newly revised Drug Administration Law, drug standards, drug inspection in the new era, quality consistency evaluation of generic drugs, pharmaceutical production and engineering, biopharmaceutical production process, ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) biotechnology product quality (Q5) guide, and ICH quality standard (Q6) guide, etc. More than 700 delegates attended the Conference.

(Excerpt from: CCFDIE website, October 17, 2019)

综合报道

2019中国制药工程大会在南昌举办

2019年10月11至13日，由中国食品药品国际交流中心、国家药品监督管理局食品药品审核查验中心与国际制药工程协会（ISPE）共同合作举办的2019中国制药工程大会在南昌成功召开。中国制药工程大会自2007年第一届开始，已经连续成功举办13届，大会形式多样，内容丰富精彩，其权威性、影响力越来越大。大会现已成为宣传我国药监法律法规、了解国外最新监管动态，分享最新制药技术，传递信息的重要平台。为推动我国制药行业发展进步、为药品生产质量安全发挥了积极的作用。

2019年中国制药工程大会由药品生产与质量管理交流会、全体大会、全国药品检查专题工作会、核查中心专场、ICH Q5专场、ICH Q6专场等六个专场会和六个技术分会组成。大会邀请了60多位来自中外药监部门以及行业协会、中外制药领域的专家和学者，分别就新修订《药品管理法》生产与质量管理新要求、药品标准、新形势下药品检查工作、仿制药质量一致性评价、生产和工程、生物药生产工艺、ICH生物技术产品质量（Q5）指南、ICH质量标准（Q6）指南等热点话题展开交流讨论。700多名代表参加了本次会议。

（摘自：中国食品药品国际交流中心网站 2019-10-17）

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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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 Fax: 010-8221 2857
Email: ccfdie@ccfdie.org
Website: www.ccfdie.org

Servier (Tianjin) Pharmaceutical Co., Ltd.
施维雅（天津）制药有限公司

Address: 6 Floor, West Building, World Financial Center, No.1, East 3rd Ring Middle Road, Chaoyang District, 100020 Beijing, China
北京市朝阳区东三环中路1号环球金融中心西楼6层
邮编：100020

Tel: 010-6561 0341
Fax: 010-6561 0348
Website: www.servier.com.cn