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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

The Eleventh Conference of the Chinese Pharmacopoeia Commission Executive Committee Held in Beijing

—Review and Approve the Draft of ChP 2020 Edition

Pursuant to the *Charter of the Chinese Pharmacopoeia Commission* and the compilation procedures of the *Pharmacopoeia of the People's Republic of China* (hereinafter referred to as *ChP*), on April 9, the 11th Conference of the Chinese Pharmacopoeia Commission (ChPC) Executive Committee was held in Beijing for a briefing on ChPC's compilation of the ChP 2020 Edition, as well as the deliberation and approval of its draft. Jiao Hong, NMPA Commissioner and Chairperson of the 11th ChPC, and Zeng Yixin, ChPC Deputy Chairman and Vice-minister of the National Health Commission attended the Conference and delivered speeches. Chen Shifei, NMPA Deputy Commissioner and ChPC Deputy Chairman, chaired the Conference. Lan Fen, Secretary General of ChPC, briefed to all executive committees on the compilation of the ChP 2020 Edition.

ChP 2020 Edition has 319 new admissions, 3177 revisions, 10 exclusions (rejections), 4 combination adjustments, and a grand sum of 5,911 monographs. Volume I-TCM contains a total of 2711 monographs, covering 117 new admissions and 452 revisions. Volume II-Chemicals contains 2712 monographs, covering 117 new admissions and 2387 revisions. Volume III-Biologicals contains 153 monographs, covering 20 new admissions, 126 revisions; and 2 new General Requirements for biological products and 4 General Monographs. Volume IV contains 361 General Technical Requirements, covering 38 General Requirements for preparations (incl. 35 revisions), 281 detection methods and other General Requirements (35 new admissions, 51 revisions), and 42 guidelines (12 new admissions, 12 revisions); and 335 monographs of medicinal excipients, including 65 new admissions and 212 revisions.

Jiao Hong pointed out that ChP 2020 Edition is steadily advancing the inclusion of pharmacopoeia monographs, which further meets the needs of the National Essential Drug List and basic medical insurance catalog varieties. The national drug standard system is becoming more and more perfect, the level of drug standards has been significantly improved, the requirements for drug safety have been continuously strengthened, and the guiding role of ChP has become increasingly significant. The promulgation and implementation of ChP 2020 will help to raise the overall level of China's pharmaceutical standards, further ensure the protection of drug safety for the public, motivate the adjustment of the pharmaceutical industry structure, and facilitate China's pharmaceutical products to go global, aiming at a leap from a big country with numerous small pharmaceutical enterprises to a big country with strong pharmaceutical enterprises.

Jiao Hong emphasized that the national drug standard is a mandatory provision made by the state on drug quality indicators and inspection methods to ensure drug quality, and a legal technical requirement that must be followed in drug production, distribution, use and supervision. The newly revised *Drug Administration Law* further aggrandizes the legal role of the national drug standard. It is necessary to continuously consolidate the legal status of ChP, reinforce the drug standard system and management capacity building, comprehensively improve the overall level of the national drug standard, and effectively promulgate and implement the new ChP, to ensure that it is well understood, implemented and supervised. (April 13, 2020)

第十一届药典委员会执行委员会会议在京召开

——审议通过2020年版《中国药典》草案

根据《药典委员会章程》以及《中华人民共和国药典》（以下简称《中国药典》）编制工作程序，4月9日，第十一届药典委员会执行委员会会议在北京召开。会议听取了国家药典委员会关于2020年版《中国药典》编制工作情况报告，审议并通过了2020年版《中国药典》草案。第十一届药典委员会主任委员、国家药品监督管理局局长焦红，副主任委员、国家卫生健康委员会副主任曾益新出席会议并讲话。副主任委员、国家药品监督管理局副局长陈时飞主持会议。国家药典委员会秘书长兰奋向全体执委汇报2020年版药典编制工作情况。

2020年版《中国药典》新增品种319种，修订3177种，不再收载10种，品种调整合并4种，共收载品种5911种。一部中药收载2711种，其中新增117种、修订452种。二部化学药收载2712种，其中新增117种、修订2387种。三部生物制品收载153种，其中新增20种、修订126种；新增生物制品通则2个、总论4个。四部收载通用技术要求361个，其中制剂通则38个（修订35个）、检测方法及其他通则281个（新增35个、修订51个）、指导原则42个（新增12个、修订12个）；药用辅料收载335种，其中新增65种、修订212种。

焦红指出，2020年版《中国药典》稳步推进药典品种收载，进一步满足了国家基本药物目录和基本医疗保险目录品种的需求。国家药品标准体系日趋完善，药品标准水平显著提升，药品安全性要求持续加强，导向性作用日益显著。其颁布实施，将有利于整体提升我国药品标准水平，进一步保障公众用药安全，推动医药产业结构调整，促进我国医药产品走向国际，实现由制药大国向制药强国的跨越。

焦红强调，国家药品标准是国家为保证药品质量，对药品的质量指标、检验方法等作出的强制性规定，是药品生产、流通、使用和监管所必须遵循的法定技术要求。新修订《药品管理法》进一步强化了国家药品标准的法定性作用，要不断巩固药典的法律地位，加强药品标准体系和管理能力建设，全面提升国家药品标准整体水平，扎实做好新版药典颁布实施和贯彻执行，确保新版药典理解到位、执行到位、监督到位。 (2020-04-13)

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Drugs

NMPA and NHC Issued the *Announcement on Good Clinical Practice*

To deepen the reform of the drug review and approval system, encourage innovation, and further promote the research and quality improvement of drug clinical practice in China, NMPA, in conjunction with NHC, has organized the revision of the *Good Clinical Practice* (GCP), which has been released on April 26, 2020, and shall enter into effect as from July 1, 2020.

(April 26, 2020)

药品

国家药品监督管理局 国家卫生健康委员会发布《关于药物临床试验质量管理规范的公告》

为深化药品审评审批制度改革，鼓励创新，进一步推动我国药物临床试验规范研究和提升质量，国家药品监督管理局会同国家卫生健康委员会组织修订了《药物临床试验质量管理规范》，于2020年4月26日发布，自2020年7月1日起施行。 (2020-04-26)

NMPA Announcement on the Release of Revised Draft of the Appendix (Biological Products) as Recorded in the *Good Manufacturing Practice for Drugs (Revised in 2010)*

With the roll out of the Drug Administration Law of the People 's Republic of China and the Vaccine Administration Law of the People 's Republic of China, NMPA has, in the light of Article 310 of the *Good Manufacturing Practice for Drugs (Revised in 2010)*, revised the Appendix (Biological Products) (as a supporting document for the GMP), which has been released on April 26, 2020, and will come into force on July 1, 2020. Among them, in view of Article 59 of the Appendix, if an enterprise records data with an information system of real time data collection, given that information construction requires a certain period, it should meet the relevant requirements prior to July 1, 2022. (April 26, 2020)

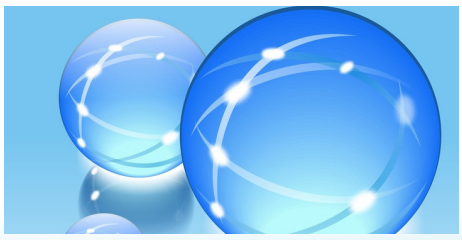
国家药品监督管理局发布《药品生产质量管理规范（2010年修订）》生物制品附录修订稿的公告

《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》实施后，国家药品监督管理局按照《药品生产质量管理规范（2010年修订）》第三百一十条规定，对《生物制品》附录进行了修订，作为《药品生产质量管理规范（2010年修订）》配套文件，于2020年4月26日予以发布。本附录自2020年7月1日起施行。其中，对于附录第59条，企业采用实时采集数据的信息化系统记录数据的，因信息化建设需要一定周期，应在2022年7月1日前符合相关要求。 (2020-04-26)

NMPA Announcement on Revising the Package Inserts for Polyene Phosphatidylcholine Injection

To further protect drug safety for the people, on May 7, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of Polyene Phosphatidylcholine Injection.

(May 7, 2020)



国家药品监督管理局发布关于修订多烯磷脂酰胆碱注射液说明书的公告

为进一步保障公众用药安全，2020年5月7日，国家药品监督管理局发布关于修订多烯磷脂酰胆碱注射液说明书的公告，决定对多烯磷脂酰胆碱注射液说明书【不良反应】、【注意事项】等项进行修订。

(2020-05-07)

NMPA Announcement on Revising the Package Inserts of Sodium Aescinate for Injection

To further ensure safe medication for the public, on May 7, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions] and other Entries on the package inserts of sodium aescinate for injection. (May 7, 2020)

国家药品监督管理局发布关于修订注射用七叶皂苷钠说明书的公告

为进一步保障公众用药安全，2020年5月7日，国家药品监督管理局发布关于修订注射用七叶皂苷钠说明书的公告，决定对注射用七叶皂苷钠说明书【不良反应】、【注意事项】等项进行修订。 (2020-05-07)

Medical devices

NMPA Issued 7 Guidances for Technical Review Including the Guidance for Technical Review of the Registration of Vertebroplasty Balloon Dilation Catheters

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 the *Guidance for Technical Review of the Registration of Vertebroplasty Balloon Dilation Catheters, Guidance for Technical Review of the Registration of Acrylic Bone Cement for Artificial Joint Replacement, Guidance for Technical Review of the Registration of Metal Intramedullary Nail System, Guidance for Technical Review of the Registration of Vaseline Gauze, Guidance for Technical Review of the Registration of Hydrocolloid Dressings, Guidance for Technical Review of the Registration of Ovum Aspiration Needles for Assisted Reproduction*, and *Guidance for Technical Review of the Registration of Spinal Implant Quality Control and Clinical Evaluation*, which have been released on May 9, 2020. (May 7, 2020)

医疗器械

国家药品监督管理局发布椎体成形球囊扩张导管等7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《椎体成形球囊扩张导管注册技术审查指导原则》《人工关节置换术用丙烯酸树脂骨水泥注册技术审查指导原则》《金属髓内钉系统产品注册技术审查指导原则》《凡士林纱布产品注册技术审查指导原则》《水胶体敷料产品注册技术审查指导原则》《辅助生殖用穿刺取卵针注册技术审查指导原则》《脊柱植入物临床评价质量控制注册技术审查指导原则》，于2020年5月9日发布。 (2020-05-09)

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

To further strengthen the supervision and inspection over sterile and implantable medical devices (including high-value medical consumables), implement the requirements of the Notice of the General Office of the State Council on the Issuance of the Reform Plan for Governance over High-value Medical Consumables (State Council General Office [2019] No. 37), fully implement the corporate principal responsibility and ensure the safety and effectiveness of medical devices, taking into account the arrangement for medical device supervision in 2020, as well as the prevention and control of the COVID-19 epidemic situation, on April 14, 2020, NMPA issued the Notice on Strengthening the Supervision and Inspection of Sterile and Implantable Medical Devices, requiring the Medical Products Administration Departments of all provinces, autonomous regions, municipalities directly under the central government and the Xinjiang Production and Construction Corps to further strengthen the supervision and inspection of sterile and implantable medical devices (including high-value medical consumables) . (April 14, 2020)

国家药品监督管理局发布关于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（含高值医用耗材）监督检查，贯彻《国务院办公厅关于印发治理高值医用耗材改革方案的通知》（国办发〔2019〕37号）要求，全面落实企业主体责任，保障医疗器械安全有效。根据2020年医疗器械监管工作安排，并结合新冠肺炎疫情防控情况，2020年4月14日，国家药品监督管理局发布关于加强无菌和植入性医疗器械监督检查的通知，要求各省、自治区、直辖市药品监督管理局，新疆生产建设兵团药品监督管理局进一步加强无菌和植入性医疗器械（含高值医用耗材）监督检查。 (2020-04-14)

NMPA Issued the Announcement on the Guidance for Medical Device Registrants to Conduct Adverse Events Monitoring

To implement the requirements of the *Provisions for the Monitoring and Re-evaluation of Medical Device Adverse Events* (SAMR and NHC Order No. 1), guide and regulate medical device registrants and applicants for record filing (hereinafter collectively referred to as registrants) to perform adverse events monitoring, NMPA has organized the formulation of and released on April 10, 2020 the *Guidance for Medical Device Registrants to Conduct Adverse Events Monitoring.*

The *Guidance for Monitoring Medical Device Adverse Events (Interim)* (CFDA [2011] No. 425) issued by the former State Food and Drug Administration shall be repealed simultaneously. (April 10, 2020)

国家药品监督管理局发布关于医疗器械注册人开展不良事件监测工作指南的通告

为落实《医疗器械不良事件监测和再评价管理办法》（国家市场监督管理总局中华人民共和国国家卫生健康委员会令第1号）要求，指导和规范医疗器械注册人、备案人（简称注册人）开展不良事件监测工作，国家药品监督管理局组织制定了《医疗器械注册人开展不良事件监测工作指南》，于2020年4月10日发布。

原国家食品药品监督管理局《医疗器械不良事件监测工作指南（试行）》（国食药监械〔2011〕425号文）废止。 (2020-04-10)

Annual Report

Annual Report for National Adverse Drug Reaction Monitoring (2019) Released

To fully reflect the status of China's adverse drug reaction (ADR) monitoring in 2019, improve the level of safe drug use, and better ensure drug safety for the public, the National Center for ADR Monitoring has organized the compilation of the *Annual Report for National Adverse Drug Reaction Monitoring (2019)*, which has been released on April 10, 2020.

- **Overall Situation of Adverse Drug Reaction Monitoring**

In 2019, in accordance with General Secretary Xi Jinping's *Four Strictest* requirements for food and drugs, the monitoring and evaluation of adverse drug reactions (ADR) has been carried out steadily and orderly, the corresponding laws and regulations have been continuously improved, the monitoring & evaluation system has gradually become robust, the quantity and quality of case reports saw an upward trend, risk control measures have become more sophisticated, and remarkable results have been achieved in relevant fields, providing strong support for drug administration.

First of all, the information system has been improved to further lay a solid foundation for monitoring and evaluation. The national ADR monitoring network system has been improved. The monitoring system for drug Marketing Authorization Holders (hereinafter referred to as MAHs) to directly report ADRs has been officially in operation, effectively promoting the MAH's ADR monitoring. We continued to forge closer ties with medical institutions and explored new models for ADR monitoring. At present, we have established outposts for ADR monitoring in 189 Class-III medical institutions. In 2019, 97.4% of county-level regions across the country reported adverse drug reactions / events (ADR / ADE). The average number of reports per million populations in China reached 1,130, which laid a solid foundation for the in-depth development of monitoring and evaluation.

Secondly, scientific evaluation is reinforced to timely deal with risk warning signals. We established and improved the working mechanism of daily monitoring, weekly summarization and quarterly analysis. At the same time, we paid close attention to the domestic and foreign regulatory dynamics in close integration with our actual clinical medication practice, and continuously strengthened the analysis and evaluation of the ADR report data. According to the

年报

《国家药品不良反应监测年度报告》（2019年）发布

为全面反映2019年我国药品不良反应监测情况，提高安全用药水平，更好地保障公众用药安全，国家药品不良反应监测中心组织编撰了《国家药品不良反应监测年度报告（2019年）》，于2020年4月10日发布。

药品不良反应监测工作情况

2019年，按照习近平总书记对食品药品“四个最严”要求，药品不良反应监测评价工作平稳有序开展，法规制度不断完善，监测评价体系逐步健全，报告数量和质量稳步提升，风险控制手段更加成熟，相关工作取得明显成效，为药品监管提供了有力支撑。

一是完善信息系统，进一步夯实监测评价工作基础。完善国家药品不良反应监测网络系统，药品上市许可持有人（以下简称持有人）直接报告药品不良反应监测系统正式运行，持有人不良反应监测工作得到有效推动。继续加强与医疗机构的合作，探索药品不良反应监测新模式，目前已在189家三级医疗机构建立药品不良反应监测哨点。2019年全国97.4%的县级地区报告了药品不良反应／事件，全国每百万人口平均报告数达到1,130份，为监测评价工作深入开展奠定了坚实的基础。

二是加强科学评价，及时处置风险预警信号。建立健全日监测、周汇总、季度分析工作机制，同时密切关注国内外监管动态，紧密结合临床用药实际，不断强化对药品

evaluation outputs, we timely released pharmacovigilance information. In 2019, we issued the *Announcement on the Cessation of Production, Sale and Use of Furazolidone-Containing Compound Preparations*, as well as 27 Announcements on the revision of drug package inserts, and 12 volumes of *Pharmacovigilance Express*. The functions of the early warning management platform were further optimized to realize early detection, response, investigation, and disposal of early-warning signals to ensure effective protection of drug safety for the public.

Thirdly, the construction of standards is strengthened, and the transformation and implementation of ICH related guidance is promoted. The *Guidance for Clinical Safety Literature Evaluation of Marketed Drugs (Interim)* and *Guidance for Compiling the Annual Pharmacovigilance Report by Marketing Authorization Holders (Interim)* were issued to guide MAHs in monitoring, reporting, analysis and evaluation. We steadily promoted the transformation and implementation of E2B (R3: Clinical Safety Data Management - Data Elements for Transmission of Individual Case Safety Reports) of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), and released the *Regional Implementation Guidance for Individual Case Safety Reports E2B(R3)*. We promoted the application of the Medical Dictionary for Regulatory Activities (MedDRA), carried out disease term mapping research, strengthened the training for MAHs and monitoring institutions, and provided technical guarantee for full swing of ICH related Guidance.

Fourthly, we actively promoted publicity and guidance over ADRs to beef up public awareness. The 7th China Pharmacovigilance Conference was held to promote academic exchange and experience sharing in this field. We organized training for ADR monitoring to guide MAHs to implement their principal responsibility for drug safety, and raise their awareness for risk management. We've made full use of the National Safe Medicine Monthly Platform, as well as the Internet, TV, newspapers and other media to actively disseminate the knowledge of adverse drug reactions; carried out various forms of activities such as public open days and joint urban-rural efforts, sparing no effort to increase public awareness of ADRs.

- **Status of ADR / ADE reporting**

(I) Overview of reporting

1. The report of ADRs / ADEs in 2019

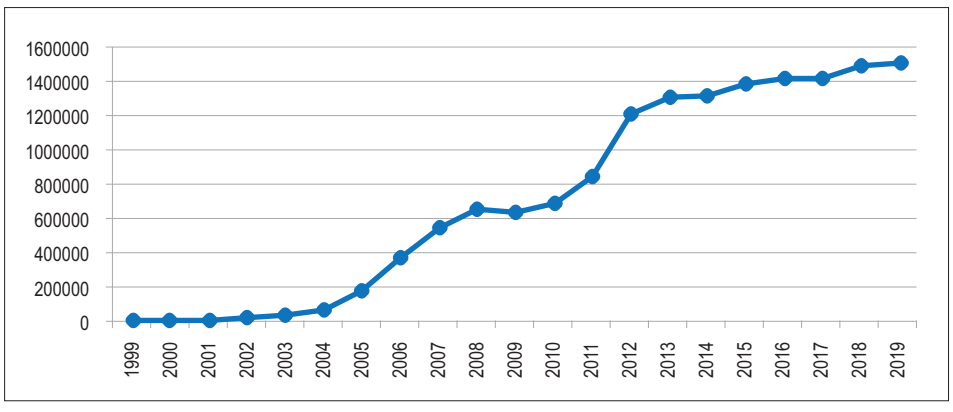
In 2019, the National ADR Monitoring Network received 1.514 million copies of *ADR / ADE Report Form*. From 1999 to 2019, the National ADR Monitoring Network received an accumulative total of 15.19 million copies of the *ADR / ADE Report Form* (See Figure 1).

2. New and serious ADR/ADE reporting

In 2019, the National ADR Monitoring Network received 477,000 new and serious ADR/ADE reports, accounting for 31.5% of the total number reported in the same period.

In 2019, the National ADR Monitoring

图1 1999年-2019年全国药品不良反应／事件报告数量增长趋势
Figure 1 1999 - 2019 growth trend of ADR/ADE reports in China



不良反应报告数据的分析评价。根据评价结果，及时发布药品安全警示信息。2019年发布停止含呋喃唑酮复方制剂生产销售使用公告，发布药品说明书修订公告27期，发布《药物警戒快讯》12期。继续优化预警管理平台功能，对预警信号做到早发现、早应对、早调查、早处置，切实保障公众用药安全。

三是强化规范建设，推进ICH相关指导原则转化实施。发布《上市药品临床安全性文献评价指导原则（试行）》《药品上市许可持有人药物警戒年度报告撰写指南（试行）》，指导持有人开展监测、报告、分析和评价工作。稳步推进国际人用药品注册技术协调会（ICH）E2B（R3）转化实施，发布《个例安全性报告E2B（R3）区域实施指南》；促进监管活动医学词典（MedDRA）应用，开展疾病术语映射研究，加强对持有人和监测机构的培训，为全面实施ICH相关指导原则提供技术保障。

四是积极宣传引导，努力提高公众对不良反应的认知度。举办第七届中国药物警戒大会，促进药物警戒领域的学术交流和经验分享。组织开展药品不良反应监测业务培训，指导持有人落实安全主体责任，强化风险管理意识。充分借助全国安全用药月平台，利用网络、电视、报纸等媒体，积极宣传药品不良反应知识，开展公众开放日和城乡携手共建等形式多样的活动，努力提高公众对药品不良反应的认知度。

药品不良反应／事件报告情况

• 报告总体情况

1. 2019年度药品不良反应／事件报告情况

2019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》151.4万份。1999年至2019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》1,519万份（图1）。

2. 新的和严重药品不良反应／事件报告情况

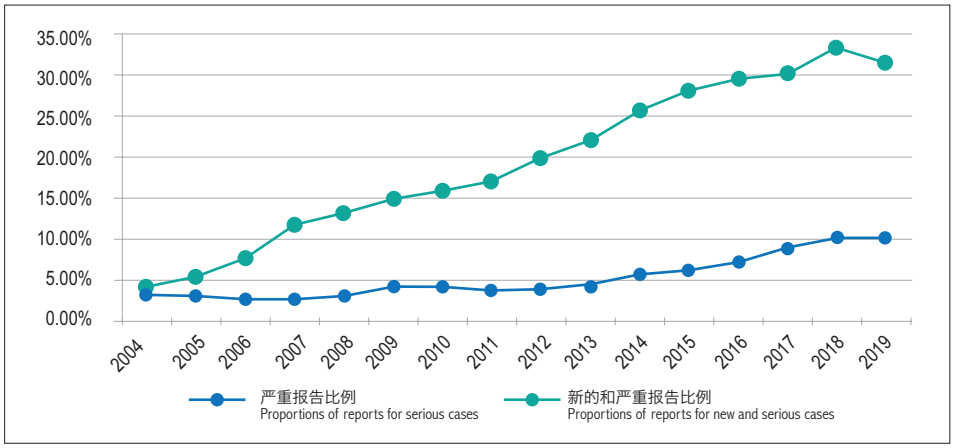
2019年全国药品不良反应监测网络收到新的和严重药品不良反应／事件报告47.7万份；新的和严重药品不良反应／事件报告占同期报告总数的31.5%。

2019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15.6万份，严重药品不良反应／事件报告占同期报告总数的10.3%（图2）。

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

图2 2004—2019年新的和严重以及严重药品不良反应／事件报告比例
Figure 2 New & serious ADR / ADE and serious ADR / ADE reports in 2004-2019



Network received 156,000 reports of serious adverse drug reactions / incidents, and serious ADR/ADE reports accounted for 10.3% of the total reports for the same period (Figure 2).

3. Average case report per million population

The average number of reports per million population constitutes one of the major indicators to measure the level of a country's ADR monitoring work. The average number of reports per million population in China marked 1,130 in 2019.

4. Proportion of ADR/ADE reports at county level *

The ratio of ADR/ADE reports at county level constitutes one of the important indicators to measure the balanced development and coverage of ADR monitoring in China. In 2019, 97.4% of county-level regions across China reported ADRs/ADEs.

5. Sources of ADR/ADE reports

MAHs, pharmaceutical distributors and medical institutions constitute the responsible units for ADR / ADE reporting. As per source-specific statistics of ADR/ADE reports in 2019, a lion's share of 88.1% came from medical institutions; while a share of 6.6%, 5.2%, and 0.1% came from pharmaceutical distributors, MAHs, individuals and other sources, respectively (Figure 3).

6. Occupations of reporters

In occupation-specific statistics, of all the reporters, doctors accounted for 56.6%, pharmacists accounted for 22.3%, nurses accounted for 15.3%, and other occupations accounted for 5.8%.

7. Patients involved in the ADR / ADE reports

In the 2019 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 10.2%; and reports of elderly patients over 65 accounted for 29.1%.

8. Distribution of drug categories involved in 2019 ADR/ADE reports

As per category-specific statistics of suspected drugs, reports of chemical drugs, TCM and bio-products accounted for 84.9%, 12.7% and 1.6%, respectively, while 0.8% of the drugs are not classifiable.

As per the statistics of routes of administration of drugs involved in 2019 ADR/ADE reports, 62.8% were administered by injection, 32.5% by oral administration, and 4.7% by other routes of administration. Among injection administrations, intravenous administration accounts for 92.5% and other injection administrations account for 7.5%.

9. Systems damaged by ADRs / ADEs

Among the ADRs/ADEs reported in 2019, the top 5 organ system damages are: skin and its appendages damage; gastrointestinal damage; systemic damage, neurological impairment and cardiovascular system damage.

(April 10, 2020)

之一。2019年我国每百万人口平均报告数为1,130份。

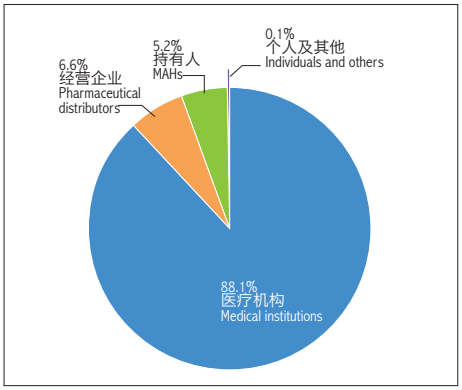
4. 药品不良反应／事件县级报告比例

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。2019年全国97.4%的县级地区报告了药品不良反应／事件。

5. 药品不良反应／事件报告来源

持有人、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，2019年来自医疗机构的报告占88.1%；来自经营企业的报告占6.6%；来自持有人的报告占5.2%；来自个人及其他报告者的报告占0.1%（图3）。

图3 2019年药品不良反应／事件报告来源分布
Figure 3 Source distribution of 2019 ADR/ADE reports



6. 报告人职业

按照报告人职业统计，医生占56.6%，药师占22.3%，护士占15.3%，其他职业占5.8%。

7. 药品不良反应／事件报告涉及患者情况

2019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岁以下儿童患者占10.2%；65岁及以上老年患者占29.1%。

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84.9%、中药占12.7%、生物制品占1.6%，无法分类占0.8%。

按照给药途径统计，2019年药品不良反应／事件报告中，注射给药占62.8%、口服给药占32.5%、其他给药途径占4.7%。注射给药中，静脉注射给药占92.5%、其他注射给药占7.5%。

9. 药品不良反应／事件累及器官系统情况

2019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。 (2020-04-10)

Annual Report for National Medical Device Adverse Event Monitoring (2019) Released

To fully reflect the monitoring of adverse events in relation to China's medical devices in 2019, the National Center for Adverse Drug Reaction Monitoring has compiled and released on April 26, 2020 the *Annual Report for National Medical Device Adverse Event Monitoring (2019)*.

- **Progress of medical device adverse event monitoring**

In 2019, China's medical device adverse event monitoring continued to adhere to the *Four Strictest (Strictest Standards, Regulation, Punishment, and Accountability)* requirements, and implemented the *Previsions for Monitoring and Re-evaluating the Adverse Events of Medical Devices* (hereinafter referred to as the *Provisions*). Taking the evaluation of medical device risks as the main line, and focusing on implementing the principal responsibility of adverse event monitoring by medical device registrants and applicants for record filing (hereinafter collectively referred to as registrants), we furthered the system construction, continuously developed the approaches for relevant publicity and training, explored in depth the monitoring and evaluation methods, and comprehensively improved risk early warning and disposal capabilities. New progresses have been made in the monitoring of medical device adverse events:

(I) Collection of medical device adverse event reports

In 2019, the National Medical Device Adverse Event Monitoring Information System received more than 390,000 reports of suspected medical device adverse events, with an average number of 297 reports per million population; 96.70% of districts and counties across China reported medical device adverse events, and the registered users at the grassroots level of the system topped 310,000, covering 19,662 medical device registrants. Compared with 2018, the number of medical device adverse event reports nationwide has remained stable, the number of registered users at the grassroots level of the system has continued to increase, and a smooth transition has been achieved from the old to the new medical device adverse event monitoring information system.

(II) Risk disposal of medical device adverse events

In 2019, the risk signal evaluation & disposal of medical device adverse events has been 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 spotted risk conditions, 3 issues of *Medical Device Adverse Event Information Notification* and 12 volumes of Medical Device Pharmacovigilance Expresses were released in 2019. The intensive monitoring of medical device adverse events continued to advance in the *13th Five-Year Plan* period, and each undertaking unit actively reviewed the previous work, sorted out product risks, and ensured the orderliness of key monitoring.

(III) Improvement of medical device monitoring capabilities

In 2019, the National Center for ADR Monitoring trained a total of more than 1,300 person-time for registrants, medical institutions, and monitoring agencies. At the same time, the Center provided teachers for Workshops organized by drug regulatory authorities at all levels on the Provisions and relevant guidance to underscore the principal responsibility of registrants and improve the capacity level of monitoring personnel, and the training results were substantial. Furthermore, the Center actively followed up IMDRF's (International Medical Device Regulatory Agency Forum) work progress on adverse event terminology & coding and patient registration data evaluation. It officially joined the national regulatory authority reporting exchange mechanism to further go global.

《医疗器械不良事件监测年度报告（2019年）》发布

为全面反映2019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（2019年）》，于2020年4月26日发布。

医疗器械不良事件监测工作进展

2019年，我国医疗器械不良事件监测工作继续坚持“四个最严”的要求，贯彻落实《医疗器械不良事件监测和再评价管理办法》（以下简称《办法》），以评价医疗器械风险为主线，以落实医疗器械注册人和备案人（以下简称注册人）不良事件监测主体责任为重点，继续加强制度体系建设、不断拓展宣传培训方式、深入探索监测评价方法、全面提升风险预警和处置能力，医疗器械不良事件监测工作取得了新的进展：

（一）医疗器械不良事件报告收集

2019年，国家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39万余份，每百万人口平均报告数为297份，全国96.70%的区县报告了医疗器械不良事件，系统基层注册用户达到31万余家，其中医疗器械注册人达19662家。与2018年相比，全国医疗器械不良事件报告数量保持平稳，系统基层注册用户数量持续增加，新旧医疗器械不良事件监测信息系统实现平稳过渡。

（二）医疗器械不良事件风险处置

2019年，医疗器械不良事件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》12期。“十三五”医疗器械不良事件重点监测工作持续推进，各承担单位积极回顾前期工作，梳理产品风险，确保重点监测工作有序开展。

（三）医疗器械监测能力提升

2019年，国家药品不良反应监测中心共培训注册人、医疗机构、监测机构人员1300余人次，同时为各级药品监管部门组织开展的《办法》及相关指导原则培训班提供师资，强化注册人主体责任，提升监测人员能力水平，取得了较好的培训效果。此外，积极跟进国际医疗器械监管机构论坛不良事件术语和编码、患者登记数据评价两个项目的工作进展，正式加入国家监管机构报告交换机制，国际化水平进一步提升。

全国医疗器械不良事件报告总体情况

• 年度报告总体情况

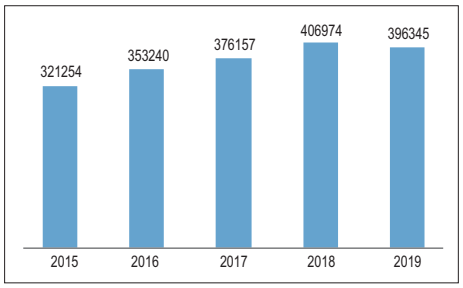
- **General situation of national medical device adverse event reporting**

(I) Overview of reporting in 2019

1. Number of Medical Device Adverse Event Report. In 2019, the National Medical Device Adverse Event Monitoring Information System has received a total of 396,345 reports of suspected medical device adverse events, a decrease of 2.61% YOY (See Figure 1) .

图1 2015—2019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 2015 to 2019 in China



2. Average number of reports per million population

In 2019, the average number of suspicious medical device adverse event reports per million population in China was 297, a decrease of 2.62% over the previous year (Figure 2).

3. County-level coverage

In 2019, the county-level coverage rate for reporting of suspected medical device adverse events in China was 96.70%, up by 0.80 percentage points YOY (Figure 3).

图2 2015—2019年全国每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 2015 to 2019

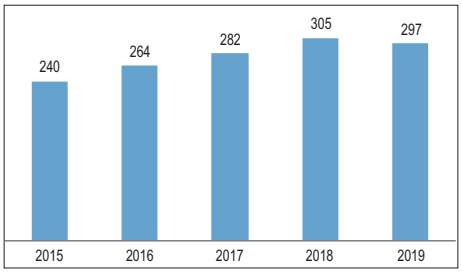
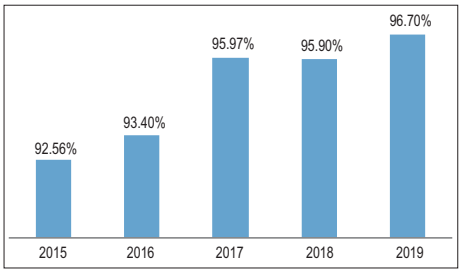


图3 2015—2019年全国可疑医疗器械不良事件报告县级覆盖率

Figure 3 County-level coverage rate for reporting of suspected medical device adverse event from 2015 to 2019 in China



(II) Number of registered grassroots users nationwide

As of December 31, 2019, there were a total of 318,986 grassroots user units (incl. registrants, distributors and user units) registered in the National Medical Device Adverse Event Monitoring Information System, covering 19,662 registrants (6.16%); 178,295 distributors (55.89%); and 121,029 user units (37.94%).

In 2019, the total number of registered grassroots users increased by 15.69% over the previous year. Among them, the registered grassroots users of registrants, distributors and user units have increased by 41.92%, 24.22% and 2.28% over 2017, respectively. (April 26, 2020)

1. 全国医疗器械不良事件报告数量。2019年，国家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396345份，比上年减少2.61%（图1）。

2. 每百万人口平均报告数量。

2019年，我国每百万人口平均可疑医疗器械不良事件报告数为297份，比上年减少2.62%（图2）。

3. 县级覆盖率。2019年，我国可疑医疗器械不良事件报告的县级覆盖率为96.70%，比上年增加0.80个百分点（图3）。

（二）全国注册基层用户数量

截至2019年12月31日，在国家医疗器械不良事件监测信息系统中注册的基层用户（包括注册人、经营企业和使用单位）共318986家，其中注册人19662家，占用户总数的6.16%；经营企业178295家，占用户总数的55.89%；使用单位121029家，占用户总数的37.94%。

2019年，注册基层用户总数比上年增长15.69%。其中，注册人注册基层用户比上年增长41.92%，经营企业和使用单位的注册基层用户分别比上年增长24.22%和2.28%。

(2020-04-26)

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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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