2021. Volume 3

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

Drugs

Notice of CDE of China NMPA on Issuing the *Technical Requirements for CMC Study and Evaluation of Chemical Drugs Marketed Overseas But Not Marketed in China (Interim)*

In order to further guide enterprises to carry out drug R&D, accelerate the R&D and marketing process of chemical drugs that have been marketed overseas but not in China, and provide technical standards that can be used as references, the CDE, under the guidance of NMPA, has organized to formulate the *Technical Requirements for CMC Study and Evaluation of Chemical Drugs Marketed Overseas But Not Marketed in China (Interim)*, which was issued and implemented as of March 3. (March 9, 2021)

Notice of CDE of China NPMA on Issuing the *Technical Guidance for CMC Changes of Innovative Drugs (Chemical Drugs) during Clinical Trials (Interim)*

In order to further cooperate with the implementation of innovative drug related policies set forth in the *Drug Administration Law and the Provisions for Drug Registration*, the CDE, under the guidance of NMPA, has organized to formulate the *Technical Guidance for CMC Changes of Innovative Drugs (Chemical Drugs) during Clinical Trials (Interim)*, which was issued and implemented as of March 3. (March 15, 2021)

Notice of CDE of China NPMA on Issuing the *Technical Guidance for Studies of Dermatological Generic Drugs for Topical Use (Interim)*

In order to guide the R&D of dermatological generic drugs for topical use in China and provide technical standards that can be used as references, the CDE, under the guidance of NMPA, has organized to formulate the *Technical Guidance for Studies of Dermatological Generic Drugs for Topical Use (Interim)*, which was issued and implemented as of March 3. (March 16, 2021)

Notice of CDE of China NMPA on Issuing the *Technical Guidance for Immunogenicity Studies of Drugs*

In order to further standardize and guide immunogenicity studies of drugs and provide technical references for the industry, researchers and regulatory authorities, the CDE, under the guidance of NMPA, has organized to formulate the Technical Guidance for Immunogenicity Studies of Drugs, which was issued and implemented as of March 5. (March 30, 2021)

药品

国家药监局药审中心关于发布《境外已上市境内未上市化学药品药学研究与评价技术要求(试行)》的通告

为进一步指导企业开展药品研发，加快境外已上市境内未上市化学药品研发上市进程，提供可参考的技术标准，在国家药品监督管理局的部署下，药审中心组织制定了《境外已上市境内未上市化学药品药学研究与评价技术要求（试行）》，于3月3日发布并施行。 (2021-03-09)

国家药监局药审中心关于发布《创新药(化学药)临床试验期间药学变更技术指导原则(试行)》的通告

为进一步配合《药品管理法》《药品注册管理办法》中关于创新药相关政策贯彻实施，在国家药品监督管理局的部署下，药审中心组织制定了《创新药（化学药）临床试验期间药学变更技术指导原则（试行）》，于3月3日发布并施行。 (2021-03-15)

国家药监局药审中心关于发布《皮肤外用化学仿制药研究技术指导原则(试行)》的通告

为指导我国皮肤外用化学仿制药研发，提供可参考的技术标准，在国家药品监督管理局的部署下，药审中心组织制定了《皮肤外用化学仿制药研究技术指导原则（试行）》，于3月3日发布并施行。 (2021-03-16)

国家药监局药审中心关于发布《药物免疫原性研究技术指导原则》的通告

为进一步规范和指导药物免疫原性研究，为工业界、研究者及监管机构提供技术参考，在国家药品监督管理局的部署下，药审中心组织制定了《药物免疫原性研究技术指导原则》，于3月5日发布并施行。 (2021-03-30)

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

Cosmetics

NMPA Announcement on Issuing the *Classification Rules and Classification Catalogue of Cosmetics*

In order to fully implement the *Regulations on the Supervision and Administration of Cosmetics* and standardize and guide the classification of cosmetics, the NMPA has formulated the *Classification Rules and Classification Catalogue of Cosmetics*, which was issued on April 8 and shall take effect as of May 1, 2021. (April 9, 2021)

NMPA Announcement on Issuing the *Standard for the Evaluation of Efficacy Claims of Cosmetics*

In order to fully implement the *Regulations on the Supervision and Administration of Cosmetics* and standardize and guide the evaluation of efficacy claims of cosmetics, the NMPA has organized to formulate the *Standard for the Evaluation of Efficacy Claims of Cosmetics*, which was issued on April 8 and shall take effect as of May 1, 2021.

(April 9, 2021)

NMPA Announcement on Issuing the *Technical Guidance for the Safety Evaluation of Cosmetics (2021 Edition)*

In order to fully implement the *Regulations on the Supervision and Administration of Cosmetics* and standardize and guide the safety evaluation of cosmetics, the NMPA has organized to formulate the *Technical Guidance for the Safety Evaluation of Cosmetics (2021 Edition)*, which was issued on April 8 and shall take effect as of May 1, 2021.

(April 9, 2021)

International Exchange

NMPA holds symposium on process and prospects of ICH in China

The National Medical Products Administration (NMPA) held a symposium on the process and prospects of the *International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use* (ICH) in Beijing on April 7 to review the progress of China's participation in the ICH and discuss follow-up work plans. Xu Jinghe, Deputy Commissioner of the NMPA, attended and spoke at the symposium.

China started to reform its drug review and approval system in 2015. China's drug regulatory authority joined the ICH in 2017, and was elected as a member of the ICH Management Committee in 2018. Since then China's drug registration administration system has accelerated its integration with

化妆品

国家药监局关于发布《化妆品分类规则和分类目录》的公告

为贯彻落实《化妆品监督管理条例》，规范和指导化妆品分类工作，国家药监局制定了《化妆品分类规则和分类目录》，于4月8日公布，自2021年5月1日起施行。

（2021-04-09）

国家药监局关于发布《化妆品功效宣称评价规范》的公告

为贯彻落实《化妆品监督管理条例》，规范和指导化妆品功效宣称评价工作，国家药监局组织起草了《化妆品功效宣称评价规范》，于4月8日公布，自2021年5月1日起施行。（2021-04-09）

国家药监局关于发布《化妆品安全评估技术导则（2021年版）》的公告

为贯彻落实《化妆品监督管理条例》，规范和指导化妆品安全评估工作，国家药监局组织起草了《化妆品安全评估技术导则（2021年版）》，于4月8日公布，自2021年5月1日起施行。（2021-04-09）

国际交流

国家药监局召开ICH中国进程与展望座谈会

4月7日，国家药品监督管理局在京召开ICH中国进程与展望座谈会，总结中国参与国际人用药品注册技术协调会（ICH）相关工作的进展，探讨后续工作计划。国家药品监督管理局党组成员、副局长徐景和出席会议并讲话。

2015年，中国启动药品审评审批制度改革。2017年，中国药监部门加入ICH，并于

international practices.

To date, China has transformed and implemented 46 ICH guidelines by issuing announcements on application or application recommendation of ICH guidelines and publishing the Chinese version of original ICH guidelines, and assigned 69 experts to participate in the in-depth coordination of ICH issues.

Deputy Commissioner Xu said that China's accession to the ICH is of great importance to both sides. In the past few years, China has attached great significance to the promotion of the rule of law in drug regulation, and has accelerated the integration of its drug regulatory policies, laws, regulations, standards and guidelines with international rules and practices. Emphasis has been put on the scientific process of drug regulation and advancing an action plan for scientific drug regulation, and close attention has been paid to the ICH's cutting-edge development to further enhance the country's perspective, keenness, flexibility and adaptability in the field. Constant efforts have also been made to deepen the reform of the drug review and approval system to keep up with international standards in terms of management measures and regulatory requirements and to maximize the innovation vitality of the pharmaceutical industry. China has also sped up construction of a guideline system and the transformation and implementation of the ICH guidelines to improve the international level of drug regulation.

It was pointed out at the meeting that the NMPA will adhere to a scientific, law-based, international and modern development path, continue to deepen reform and innovation, improve the guideline system, and accelerate the implementation of the ICH guidelines in China. More efforts will be made to comprehensively enhance exchanges and cooperation with international regulatory agencies and industries to promote international regulatory data sharing and mutual recognition. ICH related experts will also be invited to join in the training for enterprises on the implementation of the ICH guidelines. In addition, the NMPA will further participate in the formulation and revision of international standards and rules and contribute more Chinese wisdom and strength to global drug regulation.

The symposium was held online and offline simultaneously. Officials of the NMPA's relevant departments and affiliated institutions and representatives of related industry associations in Beijing attended the symposium on site. Representatives of international industry associations attended the symposium online.

The NMPA's official in charge of ICH Office briefed on the progress and follow-up plans for China's transformation and implementation of the ICH guidelines and related training and publicity programs. The official of the NMPA's Department of Drug Registration shared information on how the reform of drug review and approval system can better support the implementation of ICH guidelines.

A number of representatives from domestic and foreign industry associations were invited to the symposium.

Hong Chow, vice-chairperson of the China Association of Enterprises with the Foreign Investment R&D-based Pharmaceutical Association Committee (RDPAC), said that the reform of the drug regulatory system, including joining ICH, has strongly promoted China's drug development and pharmaceutical innovation. A new chapter in China’s pharmaceutical innovation has opened, with a remarkable increase in clinical trial applications and market approvals of innovative drugs and a rising number of innovative drugs coming into the market simultaneously both inside and outside China, she said.

The NMPA has made significant progress in implementing the ICH guidelines and has contributed to the work of the ICH Management Committee, according to Janet Vessotskie, a representative of the Pharmaceutical Research and Manufacturers of America.

Nick Cappuccino, a representative of the International Generic and Biosimilar Medicines Association (IGBA), highly affirmed and praised the Chinese government for its support for and participation in the

2018年当选为ICH管委会成员，中国药品注册管理制度加速与国际接轨。如今，中国通过发布ICH指导原则适用及推荐适用公告、发布ICH指导原则原文中文版等形式，转化实施46个ICH指导原则，并派出69名专家深入参与ICH议题协调工作。

徐景和表示，中国药监部门加入ICH，对双方都具有重要意义。过去几年，中国高度重视药品监管法治化建设，药品监管政策法规、标准、指导原则等与国际规则和实践加速接轨；高度重视药品监管科学化进程，加快推进药品监管科学行动计划，密切关注ICH前沿动态，进一步增强工作的前瞻性、敏锐性、灵活性和适应性；持续深化审评审批制度改革，在管理措施和监管要求上向国际标准看齐，最大限度激发药品产业创新活力；加快推进指导原则体系建设，积极开展ICH指导原则的转化实施工作，努力提升药品监管国际化水平。

会议指出，国家药监局将坚持科学化、法治化、国际化、现代化的发展道路，持续深化改革创新、完善指导原则体系，加速ICH指导原则在中国的落地实施；全面深化与国际监管机构和工业界的交流合作，推进国际监管数据共享和互认；邀请ICH相关专家，加大对企业实施ICH指导原则的培训力度；进一步参与国际标准规则的制修订，为全球药品监管贡献更多的中国智慧和力量。

会议采取线上线下同步进行的方式举办。国家药监局相关司局和直属单位主要负责人、相关行业学协会在京代表在现场参加会议，国际行业学协会代表在线上参会。

国家药监局ICH工作办公室负责人介绍了中国转化实施ICH指导原则和培训宣贯等工作的进展和后续计划。国家药监局药品注册司相关负责人分享了药品审评审批制度改革对更好实施ICH指导原则所给予的支持。

国内外行业学协会的多名代表受邀参加会议。中国外商投资企业协会药品研制和开发行业委员会（RDPAC）副主席周虹表示，包括加入ICH在内的药品监管体制改革有力推动了中国药品开发和医药创新，中国医药创新发展的新篇章开启，创新药的临床试验申请数量和获批上市数量明显增加，越来越多的创新药实现了在中国境内和境外同步上市。美国药品研究与制造商协会代表Janet Vessotskie认为，中国国家药监局在实施ICH指导原则方面取得了重大进展，对ICH管委会工作作出了积极贡献。国际仿制药和生物类似药协会代表Nick Cappuccino高度肯定并赞扬中国政府对ICH进程的支持和参与，希望和中方合作推动ICH关于仿制药

ICH process, and said the IGBA hopes to cooperate with China to promote the ICH process in generic drugs and biosimilars.

Other participants joining discussion at the symposium included Kang Wei, chief executive officer of the RDPAC, Pär Tellner, a representative of the European Federation of Pharmaceutical Industries and Associations, Masafumi Yokota, a representative of the Japan Pharmaceutical Manufacturers Association, Sharon Olmstead, a representative of the International Federation of Pharmaceutical Manufacturer and Associations, Xiaoqing Boynton, a representative of the Biotechnology Innovation Organization, and Aurelie Farfaro, a representative of the World Self-Medication Industry.

Participants at the symposium discussed topics such as the implementation of the ICH guidelines and deep engagement in the formulation of international rules, and spoke highly of the achievements China has made in ICH related work. (April 8, 2021)

和生物类似药议题的进程。RDPAC执行总裁康韦、欧洲制药工业协会联合会代表Pär Tellner、日本制药工业协会代表Masafumi Yokota、国际制药企业和协会联合会代表Sharon Olmstead、美国生物技术创新协会代表Xiaoqing Boynton、全球自我医疗联合会代表Aurelie Farfaro等，也参与讨论交流。与会代表围绕实施ICH指导原则、深度参与国际规则制定等话题展开探讨，对中国参与ICH相关工作所取得的成效给予高度评价。（2021-04-08）

Bilateral Meeting between China NMPA and Japan PMDA on Cooperation in Drug Supervision Was Held Online

On the afternoon of April 12, 2021, a bilateral meeting between the China National Medical Products Administration (NMPA) and the Japan Pharmaceuticals and Medical Devices Agency (PMDA) was held online for in-depth exchanges on the bilateral cooperation in drug supervision between China and Japan. Chen Shifei, Deputy Commissioner of the China NMPA, Yasuhiro Fujiwara, Chief Executive of the Japan PMDA, and relevant officials of the Japan Ministry of Health, Labor and Welfare of Japan (MHLW) attended the meeting.

Deputy Commissioner Chen said that leaders of China and Japan have reached important consensus on building China-Japanese relations that meet the requirements of the new era in recent years. The mutual support and cooperation between drug regulatory authorities of China and Japan in bilateral and multilateral areas such as ICH, is conducive to not only the common development of the two countries, but also the health of people.

Yasuhiro Fujiwara, Chief Executive of PMDA, said that China and Japan have more new opportunities for bilateral cooperation since the outbreak of COVID-19, and PMDA hopes to further strengthen amicable relations with Chinese drug regulatory authorities, continue to deepen the cooperation, and enhance the exchanges and cooperation of both parties in international organizations such as ICH, and further boost the coordination of global rules in the field of drug regulation.

At the meeting, both parties had an in-depth exchange of views on visits, information exchange and regulatory cooperation. The two parties agreed to further strengthen exchanges and cooperation to help the global fight against the pandemic and safeguard public health.

(April 14, 2021)

中日药监合作双边会议举行

2021年4月12日下午，中国国家药品监督管理局与日本药品监管机构举行双边会议，就中日双边监管合作进行深入交流。国家药品监督管理局党组成员、副局长陈时飞与日本医药品医疗器械综合机构（PMDA）理事长藤原康弘、日本厚生劳动省（MHLW）相关负责人在线参会。

陈时飞表示，近年来，中日两国领导人就推进构建契合新时代要求的中日关系达成重要共识。中日两国药监机构在双边及包括ICH等的多边领域相互支持、开展合作，既有利于双方共同发展，也有利于保障两国人民健康。

PMDA理事长藤原康弘表示，新冠肺炎疫情发生以来，中日双边合作有了更多新的合作契机，PMDA希望能进一步加强与中国药监机构的友好关系，继续深化合作，并加强双方在ICH等国际组织中的交流与合作，进一步助推全球药事监管领域规则协调。

会上，双方就开展访问交流，进行信息交换、监管合作等进行了深入交流。双方一致同意，进一步加强交流与合作，助力全球抗疫，保障公众健康。（2021-04-14）

NMPA takes part in 3rd Asian Network Meeting

The third Asian Network Meeting was held via video link on April 14.

The representatives of national drug regulatory authorities of China, India, Indonesia, Japan, South Korea, Malaysia, the Philippines, Singapore, Vietnam, and Myanmar participated in the meeting to exchange experiences and progress in combating the COVID-19 pandemic and improving the availability of innovative drugs, and for in-depth communication

第三届亚洲监管网络会议召开

2021年4月14日下午，第三届亚洲监管网络会议（Asian Network Meeting）在线召开。中国、印度、印度尼西亚、日本、韩国、马来西亚、菲律宾、新加坡、越南、缅甸的国家药品监管机构负责人参加会议，交

on further collaboration. Chen Shifei, Deputy Commissioner of China National Medical Products Administration (NMPA), attended the meeting and delivered a speech.

At the meeting, representatives of each regulatory authority introduced their measures, experiences and achievements in fighting the pandemic, including how they enhanced emergency response capabilities, reformed regulatory methods, improved accessibility of innovative products and promoted regional and national cooperation. Suggestions were also made on how to strengthen collaboration and communication.

Chen said that it is of great significance for Asian countries to share and exchange views and increase consensus on current regulatory issues of common concern. As a founding member of the Asian Regulatory Network Conference, the China NMPA will continue to contribute wisdom and strength to it. He said he hopes that all parties will continue strengthening cooperation and exchanges in drug regulation in Asia, work together to overcome COVID-19 and jointly build a global health community for all.

NMPA officials present at the meeting included those from the administration's Department of Science, Technology and International Cooperation, Department of Drug Registration, Department of Drug Regulation, Center for Drug Evaluation and Center for Food and Drug Inspection.

(Apirl 19, 2021)

流各国在应对新冠肺炎疫情、提升创新药物可及性等方面的经验和工作进展，并就进一步加强合作深入沟通。国家药品监督管理局党组成员、副局长陈时飞出席会议并致辞。

会上，各监管机构代表围绕抗击新冠肺炎疫情、增强应急能力、改革监管方式、提升创新产品可及性、促进区域和国家间协作等话题，介绍各自国家的措施、经验以及成果，研究加强合作交流的建议。

陈时飞表示，亚洲各国就当下共同关心的监管议题分享交流、增进共识至关重要。作为亚洲监管网络会议的创始成员国，中国国家药品监督管理局将继续贡献智慧和力量。希望各方继续加强在亚洲地区药品监管方面的合作交流，携手战胜新冠肺炎疫情，共建人类卫生健康共同体。

科技国合司，药品注册司，药品监管司，药审中心，核查中心有关负责同志参加会议。

(2021-04-19)

Annual Report

Annual Report for National Adverse Drug Reaction Monitoring (2020)

- **Overall Situation of the Report for Adverse Drug Reaction/Event (ADR/ADE) Monitoring**

In 2020, the China National ADR Monitoring Network received 1.676 million copies of ADR/ADE Reports. From 1999 to 2020, the National ADR Monitoring Network received a total of 16.87 million copies of ADR/ADE Reports.

In 2020, the National ADR Monitoring Network received 506,000 reports of new and serious ADRs/ADEs, accounting for 30.2% of the total number of reports in the same period.

In 2020, the National ADR Monitoring Network received 167,000 reports of serious ADRs/ADEs, accounting for 10.0% of the total number of reports in the same period.

Through the efforts of various parties, the enthusiasm of MAHs, distributors and medical institutions in ADR reporting has been gradually increased, and the number of ADR reports in China has been on the rise in general. The proportion of serious ADRs/ADEs reports is one of the important indicators to measure the overall quality and usability of reports. The collection and evaluation of new and serious ADRs has been the focus of ADR monitoring and evaluation. The increase in the number of reports of new and serious ADRs, especially reports of serious ADRs, rather than indicating the decrease in drug safety level, means that regulatory authorities have mastered the

年报

国家药品不良反应监测年度报告（2020年）

- **药品不良反应/事件监测报告总体情况**

2020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》167.6万份。1999年至2020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》1,687万份。

2020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50.6万份；新的和严重药品不良反应/事件报告占同期报告总数的30.2%。

2020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16.7万份，严重药品不良反应/事件报告占同期报告总数的10.0%。

经过各方努力，持有人、经营企业、医疗机构报告药品不良反应的积极性已经逐步提高，我国药品不良反应报告数量总体呈上升趋势。严重药品不良反应/事件报告比例是衡量报告总体质量和可利用性的重要指标之一，药品不良反应监测评价工作一直将收集和评价新的和严重反应作为重点内容。新的和严重药品不良反应报告，尤其是严重药品不良反应报告数量多了，并非说明药品安全水平下降，而意味着监管部门掌握的信息

information more comprehensively and have had more understanding of drug risks, more control over drugs and more basis for drug evaluation to make more accurate policy decision on supervision. Similarly, understanding the manifestation and degree of ADRs in medical practice in a timely manner and avoiding them to the greatest extent is also an important measure to ensure safe drug use of patients.

• Monitoring of Essential Drugs

In 2020, the National ADR Monitoring Network received a total of 830,000 ADR/ADE reports of the varieties included in the National Essential Drugs List (2018 Edition), of which 88,000 were reports of serious ADRs/ADEs, accounting for 10.6%. Reports involving chemical drugs and biological products account for 88.1% and those involving traditional Chinese medicines account for 11.9%.

The sections of chemical drugs and biological products in the National Essential Drugs List (2018 Edition) involved a total of 417 (categories) varieties. In 2020, the National ADR Monitoring Network received a total of 781,000 ADR/ADE reports of chemical drugs and biological products in the National Essential Drugs List, of which 104,000 were reports of serious ADRs/ADEs, accounting for 13.4%.

In 2020, according to the statistics of drug categories, for chemical drugs and biological products in the National Essential Drugs List, the top 5 drugs in terms of the number of reports were antimicrobial drugs, drugs for cardiovascular diseases, antineoplastic drugs, drugs for hormone and drugs for impacting endocrine system and drugs for treating mental disorders; the top 5 involved organs and systems were gastrointestinal disorders, skin and subcutaneous tissue diseases, systemic diseases and various reactions at the site of administration, nervous system disorders and examinations.

The traditional Chinese medicines in National Essential Drugs List (2018 Edition) involved a total of 268 varieties. In 2020, the National ADR Monitoring Network received a total of 105,000 ADR/ADE reports of the traditional Chinese medicine in the National Essential Drugs List, of which 6,358 were reports of serious ADRs/ADEs, accounting for 6.0%. In 2020, as for the 7 main categories of traditional Chinese medicines in the National Essential Drugs List, their descending order in terms of the total number of their ADR/ADE reports was successively internal medicine, orthopedic medicine, gynecological medicine, surgical medicine, ENT medicine, pediatric medicine, and ophthalmic medicine.

The monitoring data above demonstrate that the overall situation in 2020 of national monitoring of essential drugs remained basically stable. (March 26, 2021)

越来越全面，对药品的风险更了解，风险更可控，对药品的评价更加有依据，监管决策更加准确。同样，在医疗实践中，能及时了解药品不良反应发生的表现、程度，并最大限度地加以避免，也是保证患者用药安全的重要措施。

• 基本药物监测情况

2020年全国药品不良反应监测网络共收到《国家基本药物目录（2018年版）》收载品种的不良反应/事件报告83.0万份，其中严重报告8.8万份，占10.6%。报告涉及化学药品和生物制品占88.1%，中成药占11.9%。

《国家基本药物目录（2018年版）》化学药品和生物制品部分共417个（类）品种。2020年全国药品不良反应监测网络共收到国家基本药物化学药品和生物制品药品不良反应/事件报告78.1万例次，其中严重报告10.4万例次，占13.4%。

2020年国家基本药物化学药品和生物制品不良反应/事件报告按照药品类别统计，报告数量排名前5位的分别是抗微生物药、心血管系统用药、抗肿瘤药、激素及影响内分泌药、治疗精神障碍药；累及器官系统排名前5位的是胃肠系统疾病、皮肤及皮下组织类疾病、全身性疾病及给药部位各种反应、各类神经系统疾病以及各类检查。

《国家基本药物目录（2018年版）》中成药共涉及268个品种。2020年全国药品不良反应监测网络收到国家基本药物中成药不良反应/事件报告10.5万例次，其中严重报告6,358例次，占6.0%。2020年国家基本药物7大类中成药中，药品不良反应/事件报告总数由多到少依次为内科用药、骨伤科用药、妇科用药、外科用药、耳鼻喉科用药、儿科用药、眼科用药。

以上监测数据表明，2020年国家基本药物监测总体情况基本保持平稳。

(2021-03-26)

National Annual Report for Medical Device Adverse Event Monitoring (2020)

• Overall Situation of National Annual Report for Medical Device Adverse Events

In 2020, the National Medical Device Adverse Event Monitoring Information System has received a total of 536,055 reports of medical device adverse events, showing an increase of 35.25% compared with the previous year.

In 2020, the average number of medical device adverse event reports per million population in China was 402, showing an increase of 35.35% compared with the previous year.

国家医疗器械不良事件监测年度报告（2020年）

• 全国医疗器械不良事件年度报告总体情况

2020年，国家医疗器械不良事件监测信息系统共收到医疗器械不良事件报告536,055份，比上年增加35.25%。

2020年，我国每百万人口平均医疗器械不良事件报告数为402份，比上年增加

As of December 31, 2020, there were a total of 350,973 grassroots users (incl. registrants, distributors and using units) registered in the National Medical Device Adverse Event Monitoring Information System, covering 27,195 registrants (7.75%); 198,833 distributors (56.65%); and 124,945 using units (35.60%).

In 2020, the total number of registered grassroots users increased by 10.03% compared with the previous year. Among them, the registered grassroots users of registrants, distributors and using units have increased by 38.31%, 11.52% and 3.24% compared with the previous year, respectively.

- **Statistical Analysis of National Medical Device Adverse Event Reports**

(I) Statistical analysis according to the sources of reports

In 2020, among the medical device adverse event reports received by the National Center for ADR Monitoring, 455,782 (85.03%) were reported by using units, 11,191 (2.09%) were reported by registrants, 68,902 (12.85%) were reported by distributors, and 180 (0.03%) reports were from other sources.

(II) Statistical analysis according to the extent of injury of events

In 2020, among the medical device adverse event reports received by the National Center for ADR Monitoring, there were 218 (0.04%) reports of death, 32,874 (6.13%) reports of severe injury, and 502,963 (93.83%) reports of other injuries.

In 2020, for the medical device adverse event reports of death, the National Center for ADR Monitoring has timely took measures and urged registrants to carry out investigation and evaluation. Most of the events that have been analyzed and evaluated currently showed no clear correlation with medical devices involved. In the follow-up monitoring, no abnormal increase in the risks of medical devices involved in the above events was identified.

(III) Statistical analysis according to the management categories of medical devices

In 2020, among the medical device adverse event reports received by the National Center for ADR Monitoring, there were 178,305 (33.26%) reports involving Class III medical devices, 242,457 (45.23%) reports involving Class II medical devices, 46,995 (8.77%) reports involving Class I medical devices, and 68,298 (12.74%) reports indicating no management categories of medical devices.

(IV) Statistical analysis according to the Medical Device Classification Catalogue

In 2020, medical device adverse event reports received by the National Medical Device Adverse Event Monitoring Information System involved all categories in

35.35%。

截至2020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350,973家，其中注册人27,195家，占用户总数的7.75%；经营企业198,833家，占用户总数的56.65%；使用单位124,945家，占用户总数的35.60%。

2020年，注册基层用户总数比上年增长10.03%。其中，注册人注册基层用户比上年增长38.31%，经营企业和使用单位的注册基层用户分别比上年增长11.52%和3.24%

- **全国医疗器械不良事件报告统计分析**

（一）按报告来源统计分析

2020年，国家药品不良反应监测中心收到的医疗器械不良事件报告中，使用单位上报455,782份，占报告总数的85.03%；注册人上报11,191份，占报告总数的2.09%；经营企业上报68,902份，占报告总数的12.85%；其他来源的报告180份，占报告总数的0.03%。

（二）按事件伤害程度统计分析

2020年，国家药品不良反应监测中心收到的医疗器械不良事件报告中，伤害程度为死亡的报告218份，占报告总数的0.04%；伤害程度为严重伤害的报告32,874份，占报告总数的6.13%；伤害程度为其他的报告502,963份，占报告总数的93.83%。

2020年，对于事件伤害程度为死亡的医疗器械不良事件报告，国家药品不良反应监测中心均及时进行了处置，督促注册人开展调查、评价。在目前完成分析评价的事件中，绝大多数与涉及医疗器械无明确相关性。后续监测中，尚未发现上述事件涉及医疗器械风险异常增高情况。

（三）按医疗器械管理类别统计分析

2020年，国家药品不良反应监测中心收到的医疗器械不良事件报告中，涉及Ⅲ类医疗器械的报告178,305份，占报告总数的33.26%；涉及Ⅱ类医疗器械的报告242,457份，占报告总数的45.23%；涉及Ⅰ类医疗器械的报告46,995份，占报告总数的8.77%；未填写医疗器械管理类别的报告68,298份,占报告总数的12.74%。

（四）按医疗器械分类目录统计分析

2020年，国家医疗器械不良事件监测信息系统收到的医疗器械不良事件报告涉及了医疗器械分类目录中的所有类别。

（五）按医疗器械结构特征统计分析

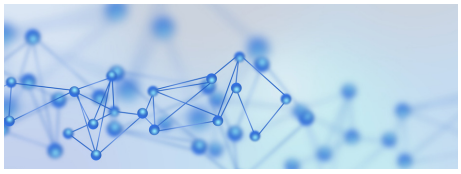
the Medical Device Classification Catalogue.

(V) Statistical analysis according to the structural characteristics of medical devices

In 2020, among the medical device adverse event reports received by the National Center for ADR Monitoring, there were 345,326 (64.42%) reports involving non-active medical devices, 118,730 (22.15%) reports involving active medical devices, 3,672 (0.69%) reports involving in vitro diagnostic reagents, and 68,327 (12.75%) reports indicating no structural characteristics of medical devices.

(VI) Statistical analysis according to the actual service site

In 2020, among the medical device adverse event reports received by the National Center for ADR Monitoring, in terms of service site, there were 459,553 (85.73%) reports showing "Medical institutions", 64,109 (11.96%) reports showing "Household", and 12,393 (2.31%) reports showing "Others". (March 29, 2021)



2020年，国家药品不良反应监测中心收到的医疗器械不良事件报告中，涉及无源医疗器械的报告345,326份，占报告总数的64.42%；涉及有源医疗器械的报告118,730份，占报告总数的22.15%；涉及体外诊断试剂的报告3,672份，占报告总数的0.69%；未填写医疗器械结构特征的报告68,327份,占报告总数的12.75%

（六）按实际使用场所统计分析

2020年，国家药品不良反应监测中心收到的医疗器械不良事件报告中，使用场所为“医疗机构”的报告459,553份，占报告总数的85.73%；使用场所为“家庭”的报告64,109份，占报告总数的11.96%；使用场所为“其他”的报告12,393份，占报告总数的2.31%。(2021-03-29)

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

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。
• 电子版Newsletter阅览请登录网站http://www.ccfdie.org

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