2017. Volume 6

CHINA FOOD AND DRUG 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

Eleven Authorities Jointly Issued a Notice to Regulate the Information Notification and Release of Food and Drug Major Illegal and Criminal Cases

Recently, the Food Safety Commission Office of the State Council, in conjunction with the Publicity Department of the Central Committee of the CPC, the Ministry of Public Security, the Ministry of Agriculture, the National Health and Family Planning Commission, the General Administration of Customs, the General Administration of Quality Supervision, Inspection and Quarantine, the China Food and Drug Administration, the Cyberspace Administration of China, the Supreme People's Court, and the Supreme People's Procuratorate, issued a Notice to raise requirements for effective information notification and release of food and drug major illegal and criminal cases.

The Notice stated that it is necessary to standardize the procedures for information notification and release, publish the authoritative information in a timely manner, and take the initiative to respond to social concerns over major illegal and criminal cases involving specific population such as infants, pregnant women, and other highly sensitive products such as vaccines, blood products, injections and dairy products, etc. Bureaus of agriculture, quality supervision, food and drug administrations and other food and drug regulatory authorities, and public security organs, procuratorial organs, anti-smuggling departments of the customs shall establish an information interoperability mechanism for case investigation and handling, promptly order to take such measures as remove from shelves, seal-up, recall, destruction of products to effectively control the safety risks of products involved, and protect public interests. Regulatory authorities should support the supervision via public opinion in the news media, whose report over food and drug illegal and criminal cases should be true to facts, rigorously expressed, and accurately worded. Without verification, "poison", "fatal", "carcinogenic" and similar words should not be used. In the events of fabricated clues and rumors that caused serious social impact, the relevant personnel shall be held legally liable as per the law.

(April 18, 2017)

11部门联合发文规范食品和药品重大违法犯罪案件信息的通报与发布工作

近日，国务院食品安全办会同中宣部、公安部、农业部、国家卫生计生委、海关总署、质检总局、食品药品监管总局、国家网信办、最高法、最高检等11个部门印发通知，就做好食品和药品重大违法犯罪案件信息的通报及发布工作提出要求。

通知称，对于涉及婴幼儿、孕产妇等特定群体，以及疫苗、血液制品、注射剂、乳制品等高敏感性产品的重大违法犯罪案件，要规范信息通报和发布的程序，及时发布权威信息，主动回应社会关切。农业、质监、食药等食品和药品监管部门与公安机关、检察机关、海关缉私部门要建立案件查办信息互通机制，及时采取责令下架、封存、召回、销毁等措施，有效控制涉案产品的安全风险，保护公众利益。监管部门要支持新闻媒体舆论监督。新闻媒体关于食品和药品违法犯罪案件的报道应实事求是、表述严谨、措辞准确。未经核实，不得使用“毒”、“致命”、“致癌”等字样。对捏造事实、制造谣言，造成严重社会影响的，要依法追究有关人员法律责任。

（2017-04-18）

Notice of the General Office of CFDA on the Issuance of *the Guide for Filing of Health Foods (Interim)*

As per relevant provisions of the *Food Safety Law of the People's Republic of China and the Provisions for Health Food Registration and Filing*, CFDA has formulated the *Guide for Filing of Health Foods (Interim)*, which was promulgated on May 2, 2017 and should be effective thenceforwards.

(May 2, 2017)

国家食品药品监督管理总局办公厅印发保健食品备案工作指南（试行）

根据《中华人民共和国食品安全法》《保健食品注册与备案管理办法》有关规定，国家食品药品监督管理总局制定了《保健食品备案工作指南（试行）》，于2017年5月2日公布，自公布之日起施行。（2017-05-02）

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

CFDA Issued the *Provisions for Useable Excipients for Health Foods Subject to Filing and Their Use (Interim)* and the *Major Manufacturing Processes of Health Foods Subject to Filing (Interim)*

As per relevant provisions of the *Food Safety Law of the People's Republic of China and the Provisions for Health Food Registration and Filing*, CFDA has formulated the *Provisions for Useable Excipients for Health Foods Subject to Filing and Their Use (Interim)* and the *Major Manufacturing Processes of Health Foods Subject to Filing (Interim)*, which were issued on May 2, 2017.

The useable excipients and major manufacturing processes of health foods subject to filing should be subject to adjustment and supplement, as appropriate, based on health food registration approval.

(May 2, 2017)

国家食品药品监督管理总局印发《保健食品备案产品可用辅料及其使用规定（试行）》《保健食品备案产品主要生产工艺（试行）》

根据《中华人民共和国食品安全法》《保健食品注册与备案管理办法》有关规定，国家食品药品监管总局制定了《保健食品备案产品可用辅料及其使用规定（试行）》《保健食品备案产品主要生产工艺（试行）》，于2017年5月2日印发。

食品备案产品可用辅料和主要生产工艺将根据保健食品注册批准情况适时调整和增补。（2017-05-02）

Two National Standards for Food Safety Incl. the *National Food Safety Standard: Maximum Levels of Mycotoxins in Foods* (GB 2761-2017) Promulgated

As per the *Food Safety Law of the People's Republic of China and the Administrative Measures for the National Food Safety Standards*, on April 20, 2017, CFDA promulgated the *National Food Safety Standard: Maximum Levels of Mycotoxins in Foods* (GB 2761-2017), and the National Food Safety Standard: Maximum Levels of Contaminants in Foods (GB 2762-2017), which have been examined and approved by the National Food Safety Standard Review Committee.

(April 20, 2017)

《食品安全国家标准食品中真菌毒素限量》（GB 2761-2017）等2项食品安全国家标准发布

根据《中华人民共和国食品安全法》和《食品安全国家标准管理办法》规定，经食品安全国家标准审评委员会审查通过，2017年4月20日，国家食品药品监督管理总局发布《食品安全国家标准食品中真菌毒素限量》（GB 2761-2017）、《食品安全国家标准食品污染物限量》（GB 2762-2017）等2项食品安全国家标准。（2017-04-20）

Nine National Standards for Food Safety Incl. the *National Food Safety Standard: Determination of Lead in Foods* (GB 5009.12-2017) Promulgated

As per the *Food Safety Law of the People's Republic of China and the Administrative Measures for the National Food Safety Standards*, on April 20, 2017, CFDA promulgated 9 national standards for food safety including the *National Food Safety Standard: Determination of Lead in Foods* (GB 5009.12-2017), which have been examined and approved by the National Food Safety Standard Review Committee.

(April 20, 2017)

《食品安全国家标准食品中铅的测定》（GB 5009.12-2017）等9项食品安全国家标准发布

根据《中华人民共和国食品安全法》和《食品安全国家标准管理办法》规定，经食品安全国家标准审评委员会审查通过，2017年4月20日，国家食品药品监督管理总局发布《食品安全国家标准食品中铅的测定》（GB 5009.12-2017）等9项食品安全国家标准。（2017-04-20）

Medical Devices

Announcement of CFDA on Approving and Issuing 28 Medical Device Industry Standards Including the *Plasmapheresis Centrifuge Apparatus for Single Use*

CFDA has examined and approved 28 Medical Device Industry Standards including YY/T 0326-2017 *Plasmapheresis Centrifuge Apparatus for Single Use*, which were issued on May 5, 2017 and should be implemented as of April 1, 2018. (May 5, 2017)

Provisions for Medical Device Standards Promulgated

On April 27, 2017, CFDA issued the *Provisions for Medical Device Standards* (CFDA Order No. 33), which include General Provisions, Responsibilities for the Management of Standards, Development and Revision of Standards, Implementation and Supervision of Standards, and Supplementary Provisions, with a total of 36 Articles in 5 Chapters, and shall come into effect as from July 1, 2017. The original *Measures for Medical Device Standards (Interim)* (CFDA Order No. 31) shall be repealed simultaneously.

(April 24, 2017)

The General Office of CFDA issued the *Notice on Working Rules for the Technical Committee on Medical Device Classification of CFDA*

To strengthen and regulate the work management of the Technical Committee on Medical Device Classification of CFDA, CFDA has formulated the *Working Rules for the Technical Committee on Medical Device Classification of CFDA*, which was issued on April 14, 2017. (April 14, 2017)

Annual Report

Annual Report for National Adverse Drug Reaction Monitoring (2016) Released

On April 28, CFDA issued the 2016 *Annual Report for National Adverse Drug Reaction Monitoring*, which is divided into four parts to introduce the overall progress of adverse drug reaction (ADR) monitoring, the ADR reporting status, the risk control measures, and the five key issues of concern in 2016. Among them, the adverse drug reaction/event (ADR/ADE) reporting is as follows:

ADR/ADE reporting

(A) Overview of reporting

1. 2016 annual ADR/ADE reporting

In 2016, the National Adverse Drug Reaction Monitoring Network has received

医疗器械

国家食品药品监督管理总局批准发布《一次性使用离心式血浆分离器》等28项医疗器械行业标准的公告

YY/T 0326—2017《一次性使用离心式血浆分离器》等28项医疗器械行业标准已经审定通过，国家食品药品监督管理总局于2017年5月5日予以公布。标准自2018年4月1日起实施。 (2017-05-05)

《医疗器械标准管理办法》颁布

2017年4月27日，国家食品药品监督管理总局发布《医疗器械标准管理办法》（国家食品药品监督管理总局令第33号）。办法包括总则、标准管理职责、标准制定与修订、标准实施与监督、附则，共5章36条，自2017年7月1日起施行。原国家药品监督管理局令第31号《医疗器械标准管理办法（试行）》同时废止。 (2017-04-24)

国家食品药品监督管理总局办公厅印发《国家食品药品监督管理总局医疗器械分类技术委员会工作规则的通知》

为加强和规范国家食品药品监督管理总局医疗器械分类技术委员会工作管理，国家食品药品监督管理总局制定了《国家食品药品监督管理总局医疗器械分类技术委员会工作规则》，于2017年4月14日印发。

(2017-04-14)

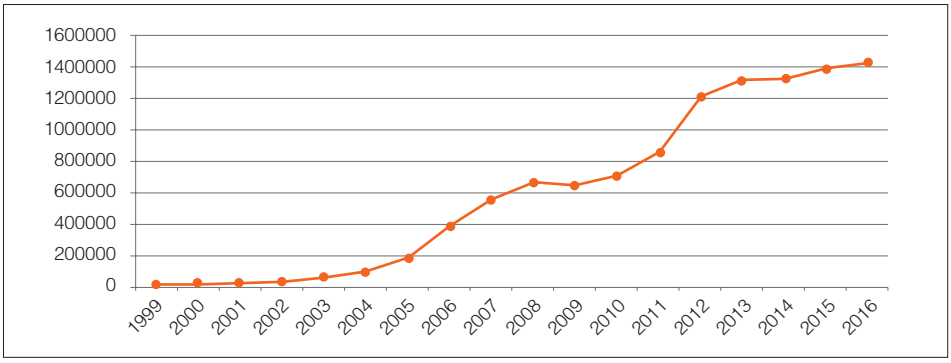
年报

《国家药品不良反应监测年度报告（2016年）》发布

2017年4月28日，国家食品药品监督管理总局发布2016年《国家药品不良反应监测年度报告》。报告分四部分介绍了2016年药品不良反应监测工作总体进展、药品不良反应报告情况、风险控制措施情况以及重点提示关注等五方面内容。其中，药品不良反应/事件报告情况如下：

a total of 1.43 million copies of ADR/ADE Report Forms, up by 2.3% YOY. From 1999 to 2016, the National Adverse Drug Reaction Monitoring Network has received a total of nearly 10.75 million copies of ADR/ADE Report Forms.

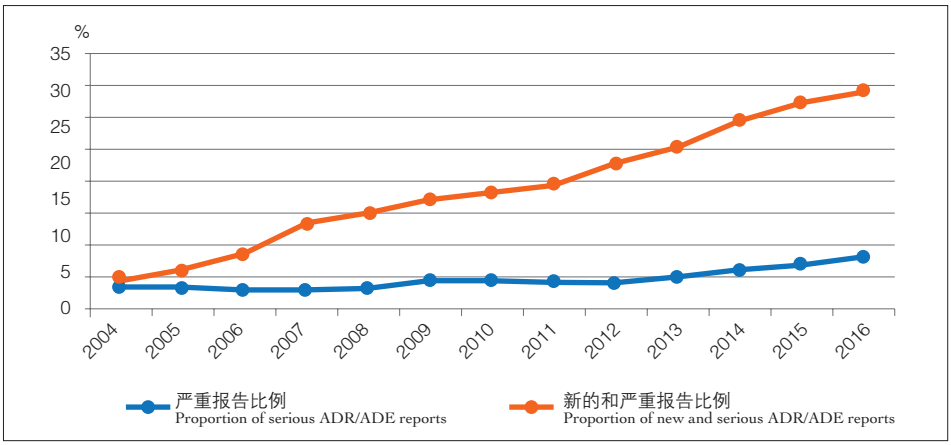
图1. 1999—2016年全国药品不良反应/事件报告数量增长趋势
Figure 1. 1999-2016 growth trend of ADR/ADE reports in China



2. New and serious ADR/ADE reports

In 2016, the National Adverse Drug Reaction Monitoring Network received more than 0.423 million copies of new and serious ADR/ADE reports, up by 7.4% YOY; new and serious reports accounted for 29.6% of the total number of reports in 2016, up by 1.4 percentage points YOY. The proportion of new and serious ADR/ADE reports continued to increase, indicating that the overall availability of ADR reports in China continues to rise.

图2. 2004—2016年新的和严重以及严重药品不良反应/事件报告比例
Figure 2. Proportions of new and serious ADR/ADE reports and serious ADR/ADE reports in 2004-2016



3. The average number of case reports per million population

The number of cases reported per million population is an important indicator to measure the level of adverse drug monitoring in a country. In 2016, the average number of case reports per million population in China was 1,068, up by 2.4% YOY.

4. Proportion of ADR/ADE county reports

Proportion of ADR/ADE county reports is an important indicator to measure the balanced development and the coverage of China's ADR monitoring in China. In 2016, the proportion of ADR/ADE county reports was 97.7% in 2016, up by 1.1 percentage points YOY.

5. Source of ADR/ADE reports

Pharmaceutical manufacturers, distributors and medical institutions constitute the responsible units for ADR reporting. As per the statistics of the sources of ADR/ADE reports in 2016, a lion's share of 85.6% came from medical institutions; while a

药品不良反应/事件报告情况

（一）报告总体情况

1. 2016年度药品不良反应/事件报告情况

2016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》143万份，较2015年增长了2.3%。1999年至2016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》近1075万份。

2. 新的和严重药品不良反应/事件报告情况

2016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42.3万余份，与2015年比增长了7.4%；新的和严重报告数量占同期报告总数的29.6%，与2015年比增加了1.4个百分点。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总体报告可利用性持续增加。

3. 每百万人口平均病例报告情况

每百万人口平均病例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。2016年我国每百万人口平均病例报告数为1068份，与2015年相比增加了2.4%。

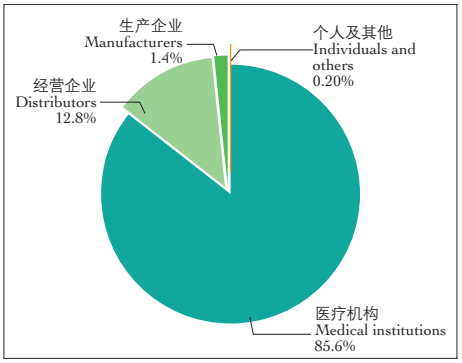
4. 药品不良反应/事件县级报告比例

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。2016年全国药品不良反应/事件县级报告比例为97.7%，与2015年相比增长了1.1个百分点。

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。2016年药品不良反应/事件报告按照来源统计，来自医疗机构的报告占85.6%；来自药品经营企业的报告占12.8%；来自药品生产企业的报告占1.4%；来自个人及其他的报告占0.2%。

图3. 2016年药品不良反应/事件报告来源分布
Figure 3. Source distribution of 2016 ADR/ADE reports

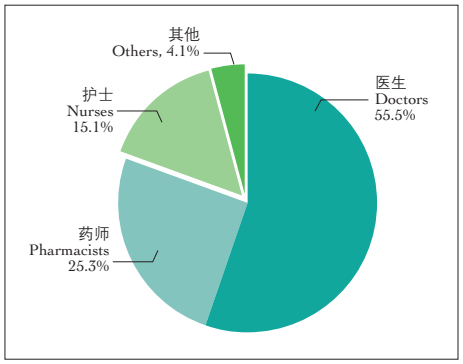


share of 12.8%, 1.4%, and 0.2% came from pharmaceutical distributors, manufacturers, individuals and other sources, respectively.

6. Occupations of reporters

According to the statistics of reporters' occupations, doctors' reports, pharmacists' reports, nurses' reports and reports by others accounted for 55.5%, 25.3%; 15.1%, and 4.1%, respectively, of the total reports. The occupational structure of reporters in 2016 is basically the same as that in 2015.

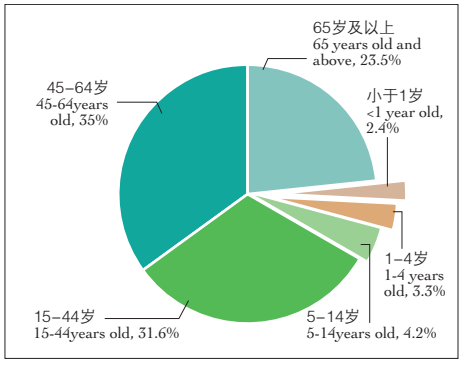
图4. 报告人职业构成
Figure 4. Occupational structure of reporters



7. Patients involved in the ADR/ADE reports

As per the statistics of gender distribution of patients involved, the male to female ratio among patients is close to 0.89:1, women slightly outnumber men, and the gender distribution trend are basically the same as that in 2015. In the 2016 ADR/ADE case reports, reports on pediatric patients under 14 years old accounted for 9.9%, basically leveled with those in 2015; reports on the elderly over 65 years old accounted for 23.5%, up by 2.0 percentage points compared with those in 2015.

图5. 2016年药品不良反应/事件报告年龄分布
Figure 5. Age-group distribution of 2016 ADR/ADE reports

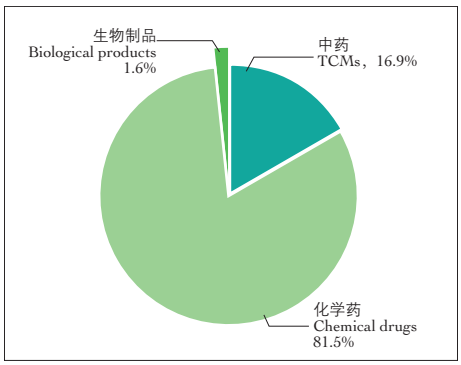


8. Distribution of drug varieties involved in ADR/ADE reports

According to variety-specific statistics of suspected drugs, reports on chemical drugs, TCMs and biological products (excluding vaccines) accounted for 81.5%, 16.9% and 1.6%, respectively, which are basically the same as those in 2015.

According to the statistics of routes of administration of drugs involved in 2016 ADR/ADE reports, the intravenous administration accounted for 59.7%; other injections (such as: intramuscular injection, and subcutaneous injection, etc.) accounted for 3.4%; oral administration accounted for 33.7%; and other administration routes (such as: topical, and patch, etc.) accounted for 3.2%. Compared with that in 2015, the overall distribution of routes of administration saw no significant changes.

图6. 2016年药品不良反应/事件报告涉及药品类别分布
Figure 6. Distribution of drug varieties involved in 2016 ADR/ADE reports



9. Organ systems damaged by ADRs/ADEs

According to 2016 ADR/ADE reports, the top three damages to organ systems are: damage to skin and its appendages (27.6%); gastrointestinal system damage (25.4%); and systemic damage (10.9%). The top three damages to systems by chemical drugs and TCMs are consistent with the overall sorting; but the top three damages to systems by biological products, which are, from high to low, damage to skin and its appendages, systemic damage and immune dysfunctions, are slightly different with the overall sorting.

6. 报告人职业

按照报告人职业统计，医生报告占55.5%，药师报告占25.3%，护士报告占15.1%，其他报告占4.1%。与2015年的报告人职业构成情况基本相同。

7. 药品不良反应/事件报告涉及患者情况

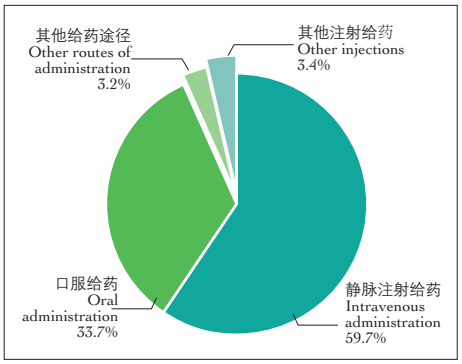
男性和女性患者比例接近0.89:1，女性略多于男性，性别分布趋势和2015年基本一致。2016年药品不良反应/事件病例报告中，14岁以下儿童患者的报告占9.9%，与2015年持平；65岁以上老年患者的报告占23.5%，较2015年有升高了2.0个百分点。

8. 药品不良反应/事件报告涉及药品情况

按怀疑药品类别统计，化学药占81.5%、中药占16.9%、生物制品（不含疫苗）占1.6%，与2015年基本一致。

按照药品给药途径统计，2016年药品不良反应/事件报告涉及的药品给药途径分布中，静脉注射给药占59.7%、其他注射给药（如：肌内注射、皮下注射等）占3.4%、口服给药占33.7%、其他给药途径（如：外用、贴剂等）占3.2%。与2015年相比，总体给药途径分布无明显变化。

图7. 2016年药品不良反应/事件报告给药途径分布
Figure 7. Distribution of routes of administration in 2016 ADR/ADE reports



9. 药品不良反应/事件累及器官系统情况

2016年报告的药品不良反应/事件中，累及系统排名前三位的为皮肤及其附件损害（占27.6%）、胃肠系统损害(占25.4%)和全身性损害（占10.9%）。化学药、中成药累及系统前三位排序与总体情况一致，生物制品累及系统前三位与总体情况略有不同，依次是皮肤及其附件损害、全身性损害及免疫功能紊乱。

10. 药品不良反应/事件报告总体情况分析

2016年药品不良反应/事件报告总体情况与2015年相比未出现显著变化。

从药品不良反应/事件报告来源看，医

10. Overall analysis of ADR/ADE reports

Overall ADR/ADE reports in 2016 show no significant changes as compared to those in 2015.

In terms of the sources of ADR/ADE reporting, the number of reports from medical institutions accounted for 85.6%, up by 3.4 percentage points YOY, doctors' reports accounted for 55.5%, up by 1.5 percentage points YOY, indicating that the medical institutions are still the mainstay for ADR/ADE reporting. The number of reports from the pharmaceutical manufacturers basically leveled with that in the last year, which is still low, indicating that there is still much leeway for pharmaceutical manufacturers to reinforce ADR monitoring; they should further strengthen their understanding of ADR monitoring and the safety study of marketed drugs, establish risk management system, enhance corporate responsibility consciousness, and timely prevent and control risks, to give full play to their "principal responsibility for drug safety". (April 28, 2017)

疗机构占比85.6%、与2015年相比来自医疗机构的报告增加了3.4个百分点，医生报告占比55.5%、与2015年相比增加了1.5个百分点，表明医疗机构仍发挥药品不良反应报告的主渠道作用；来自于药品生产企业的报告数与去年持平，报告数量仍偏低，表明药品生产企业开展不良反应监测工作的努力程度不够；作为药品生产企业，应进一步加强自身对药品不良反应工作的认识，加强上市药品的安全性研究，建立风险管理制度，强化企业责任意识，及时预防和控制风险，充分发挥“药品安全第一责任人”的责任。

（2017-04-28）

Annual Report for National Medical Device Adverse Event Monitoring (2016) Released

On May 10, 2017, CFDA issued the *Annual Report for National Medical Device Adverse Event Monitoring (2016)*, which is excerpted as follows:

I. Overview of national medical device adverse event reporting

In 2016, the national medical device adverse event monitoring saw a continued steady development, the number of suspected medical device adverse event reports topped 350,000 copies. Along with the continued growth in the number of reports, the quality of adverse event reporting also improved significantly, which has provided a basis for medical device post-marketing risk analysis and assessment.

(A) Overview of national suspected medical device adverse event reporting in 2016

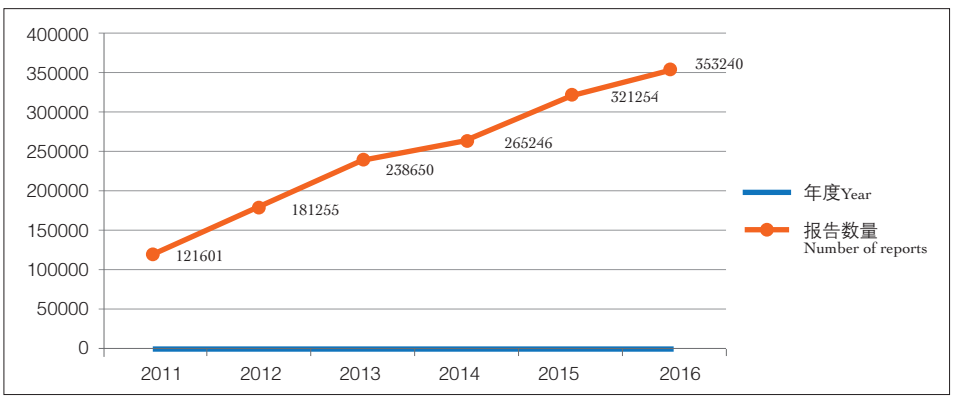
1. The numbers of national suspected adverse event reports in 2002-2016

In 2016, the National Center for ADR Monitoring has received a total of 353,240 copies of Report Form for Suspected Medical Device Adverse Events, up by 10.0% YOY (see Fig. 1-1). From January 1, 2002 to December 31, 2016, the National Center for ADR Monitoring has received a total of 1,675,299 copies of Report Form for Suspected Medical Device Adverse Events.

2. The number of suspected adverse event reports on death & serious injury

In 2016, the National Center for ADR Monitoring has received 52,331 suspected adverse event reports on serious injury, and 181 suspected adverse event reports

图1-1. 2011—2016年全国可疑医疗器械不良事件报告数量
Fig. 1-1 The numbers of national suspected medical device adverse event reports in 2011-2016



《国家医疗器械不良事件监测年度报告（2016年度）》发布

2017年5月10日，国家食品药品监督管理总局发布《国家医疗器械不良事件监测年度报告（2016年度）》。第一部分内容如下：

一、全国医疗器械不良事件报告总体情况

2016年，全国医疗器械不良事件监测工作继续稳步发展，全年可疑医疗器械不良事件报告数已超过35万份。在报告数量持续增长的同时，报告质量也不断提升，为医疗器械上市后风险的分析与评价提供了依据。

（一）2016年全国可疑不良事件报告总体情况

1. 2002年至2016年全国可疑不良事件报告数量

2016年，国家药品不良反应监测中心共收到《可疑医疗器械不良事件报告表》353240份，比2015年增长了10.0%（图1-1）。2002年1月1日至2016年12月31日，国家药品不良反应监测中心累计收到《可疑医疗器械不良事件报告表》1,675,299份。

2. 死亡及严重伤害可疑不良事件报告数量

2016年，国家药品不良反应监测中心共收到严重伤害可疑不良事件报告52,331份，死亡可疑不良事件报告181份，共计52,512份，比2015年增长了11.1%（图1-2）。2016年死亡及严重伤害可疑不良事件报告数量占报告总数的比例为14.9%，比2015年增长了0.2%。

on death, totaling 52,512 cases, up by 11.1% YOY (see Fig. 1-2). The number of suspected adverse event reports on death and serious injury in 2016 accounts for 14.9% of the total, up by 0.2% YOY.

3. Average number of reports per million population

In 2016, China's average number of reports on suspected medical device adverse events per million population was 264, up by 24 cases YOY (see Fig. 1-3).

(B) The number of registered grassroots users

图1-2. 2011—2016年全国死亡及严重伤害可疑不良事件报告数比较
Fig. 1-2 A comparison of the numbers of national suspected adverse event reports on death & serious injury in 2011-2016

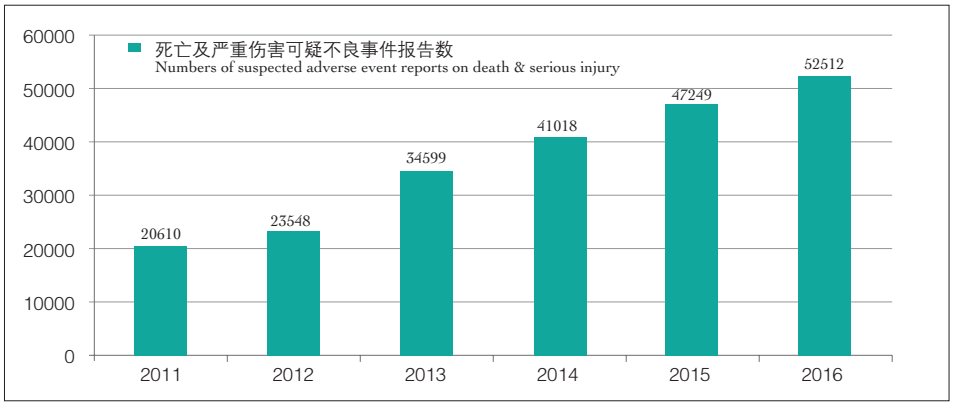
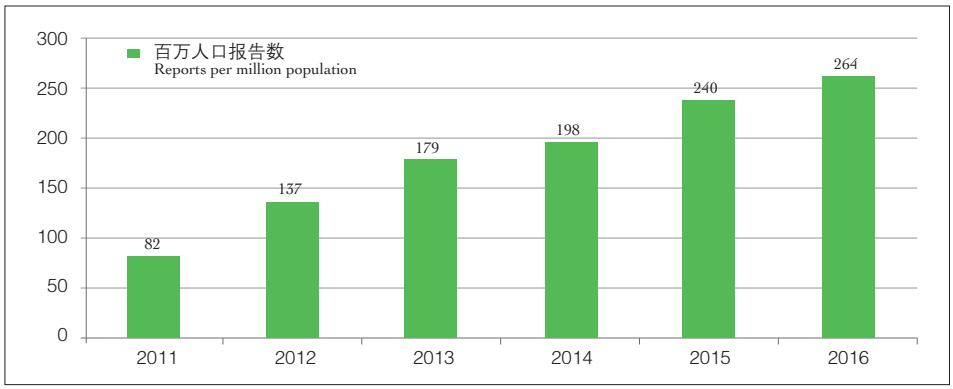


图1-3. 2011—2016年全国每百万人口平均报告数比较
Fig. 1-3 A comparison of national average numbers of reports per million population in 2011-2016



As of December 31, 2016, in the national medical device adverse event monitoring system, there were a total of 231,872 registered grassroots users (including medical device manufacturers, distributors and user units). Among them, there were 10,534 medical device manufacturers, 115,622 distributors, and 105,716 user units, accounting for 4.5%, 49.9% and 45.6% of the total registered grassroots users, respectively (see Fig. 1-4).

In 2016, the total number of registered grassroots users (including medical device manufacturers, distributors and user units) increased by 16.8% YOY. Among them, the numbers of registered medical device manufacturers, distributors and user units increased by 1.8%, 26.6% and 9.1% YOY, respectively (see Fig. 1-5).

图1-4. 2016年全国医疗器械不良事件监测系统注册基层用户情况
Fig. 1-4 The situation of registered grassroots users in the national medical device adverse event monitoring system in 2016

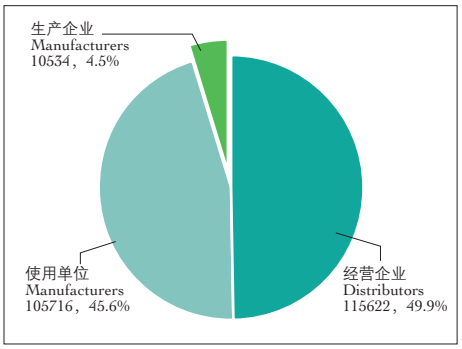
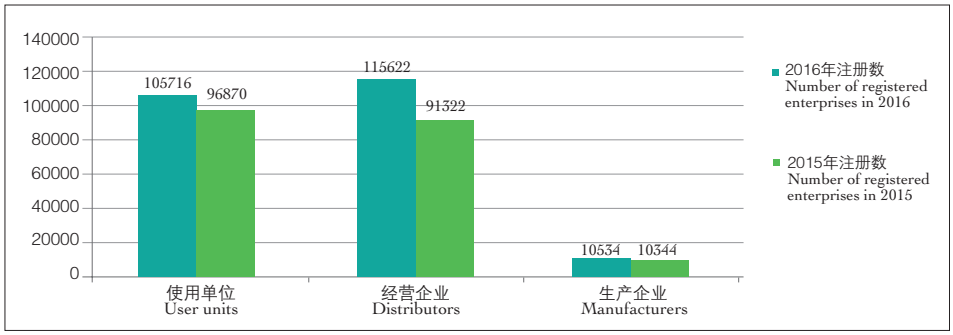


图1-5. 2015年和2016年全国注册基层用户分类比较情况
Fig. 1-5 Comparison of classification of national registered grassroots users in 2015 and 2016



(May 10, 2017)

3. 每百万人口平均报告数量

2016年，我国每百万人口平均可疑医疗器械不良事件报告数为264份，与2015年相比增长了24份（图1-3）。

（二）注册基层用户数量

截止2016年12月31日，在全国医疗器械不良事件监测系统中，注册基层用户（包括医疗器械生产企业、经营企业和使用单位）共231,872家。其中，医疗器械生产企业10,534家，占注册基层用户总数的4.5%；经营企业115,622家，占注册基层用户的49.9%；使用单位105,716家，占注册基层用户的45.6%（图1-4）。

2016年，注册基层用户（包括医疗器械生产企业、经营企业和使用单位）总数比2015年增长了16.8%。其中，医疗器械生产企业、经营企业和使用单位的注册基层用户分别比2015年增长了1.8%、26.6%和9.1%（图1-5）。 (2017-05-10)

Performance of Key Economic Indicators of the Pharmaceutical Industry in 2016

On April 20, 2017, the website of the Ministry of Industry and Information Technology published the Performance of Key Economic Indicators of the Pharmaceutical Industry in 2016, parts of which are as follows:

I. The industrial added value

In 2016, the industrial added value of above-scale pharmaceutical enterprises increased by 10.6% YOY, and the growth rate was up by 0.8 percentage points year on year (YOY), higher than the national industrial overall growth rate by 4.6 percentage points, ranking in the forefront of the whole industry.

II. The main business income

In 2016, the main business income of above-scale enterprises in the pharmaceutical industry was 2.963586 trillion RMB, up by 9.92% YOY, the growth rate was up by 0.90 percentage points YOY, higher than the national industrial overall growth rate by 5.02 percentage points.

III. Total profit

In 2016, the above-scale enterprises in the pharmaceutical industry realized a total profit of 321.643 billion RMB, up by 15.57% YOY. The growth rate was up by 3.35 percentage points YOY, higher than the national industrial overall growth rate by 7.07 percentage points.

IV. Exports

In 2016, the above-scale enterprises in the pharmaceutical industry achieved an export delivery value of 194.88 billion RMB, up by 7.26%, the growth rate was up by 3.66 percentage points YOY. As per the import and export data at customs, exports of pharmaceutical products in 2016 amounted to 55.414 billion US dollars, down by 1.82% YOY, the growth rate fell by 4.52 percentage points YOY.

V. Investment in fixed assets

In 2016, the pharmaceutical industry has realized the investment with a total of 629.9 billion RMB in fixed assets, up by 8.4% YOY.

(Source: MIIT website. April 20, 2017)

2016年医药工业主要经济指标完成情况

2017年4月日，工信部网站发布了2016年医药工业主要经济指标完成情况，部分内容如下：

一、工业增加值

2016年规模以上医药工业增加值同比增长10.6%，增速较上年同期提高0.8个百分点，高于全国工业整体增速4.6个百分点，位居工业全行业前列。

二、主营业务收入

2016年医药工业规模以上企业实现主营业务收入29635.86亿元，同比增长9.92%，增速较上年同期提高0.90个百分点，增速高于全国工业整体增速5.02个百分点。

三、利润

2016年医药工业规模以上企业实现利润总额3216.43亿元，同比增长15.57%，增速较上年同期提高3.35个百分点，高于全国工业整体增速7.07个百分点。

四、出口额

2016年医药工业规模以上企业实现出口交货值1948.80亿元，同比增长7.26%，增速较上年同期提高3.66个百分点。根据海关进出口数据，2016年医药产品出口额为554.14亿美元，同比减少1.82%，增速较上年下降4.52个百分点。

五、固定资产投资

2016年医药制造业完成固定资产投资6299亿元，同比增长8.4%。

（摘自：工信部网站 2017-04-20）

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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