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中国食品药品国际交流中心
SERVIER
施维雅（天津）制药有限公司

General Office of State Council Issued the *Opinions on Reforming and Improving the Policies for Supply, Guarantee and Use of Generic Drugs*

Recently, the General Office of State Council issued the *Opinions on Reforming and Improving the Policies for Supply, Guarantee and Use of Generic Drugs*. The Opinions pointed out that reforms to improve the policies for supply, guarantee and use of generic drugs are of great significance to the people's safety in drug use and the healthy development of the pharmaceutical industry. It proposes to promote the R&D of generic drugs, focus on addressing the undersupply of high-quality generic drugs, adhere to a problem-oriented approach and improve the quality & efficacy of generic drugs. The support policies shall be improved to expedite the clinical use of high-quality generic drugs.

(April 4, 2018)

国务院办公厅印发《关于改革完善仿制药供应保障及使用政策的意见》

日前，国务院办公厅印发《关于改革完善仿制药供应保障及使用政策的意见》。《意见》指出，改革完善仿制药供应保障及使用政策，事关人民群众用药安全，事关医药行业健康发展。《意见》提出，要促进仿制药研发，重点解决高质量仿制药紧缺问题；要突出问题导向，提升仿制药质量疗效；要完善支持政策，推动高质量仿制药尽快进入临床使用。

（2018-04-04）

Announcement of State Administration for Market Regulation and National Drug Administration on Effective Food and Drug Supervision during Institutional Reform Issued

On April 10, 2018, State Administration for Market Regulation (SAMR) and National Drug Administration jointly issued the *Announcement on Effective Food and Drug Supervision during Institutional Reform*, which reads as follows:

As per the *Decision of the CPC Central Committee on Deepening the Institutional Reform of the Party and the State and the Decision of the First Session of the 13th National People's Congress on the Institutional Reform Plan of the State Council*, SAMR shall be established as an institution directly under State Council; National Drug Administration shall be established and administered by SAMR, while the former China Food and Drug Administration (CFDA) shall be no longer retained. The current institutional reform is well under way.

During this period prior to the publication of the "Three-Determinations (of posts, duties and staffing)" Plan of SAMR and National Drug Administration, the proceedings borne by the former CFDA for supervision over foods, drugs, medical devices, cosmetics, health foods, infant formula milk powder, and foods for special medical purposes and the corresponding review & approval, supervisory inspection, examination & testing, auditing & law enforcement, complaints & reports, and information disclosure, etc., shall still be subject to the original regulations. For the time being, all types of approval letters, certificates, and paperwork shall follow the original format, with no abrupt changes in the official seals, text formats, and handling procedures. After the institutional reform is in place, the related matters shall be announced separately.

(April 10, 2018)

《国家市场监督管理总局国家药品监督管理局关于做好机构改革期间食品药品监管工作的公告》发布

2018年4月10日，国家市场监督管理总局国家药品监督管理局发布《关于做好机构改革期间食品药品监管工作的公告》，内容如下：

根据《中共中央关于深化党和国家机构改革的决定》《第十三届全国人民代表大会第一次会议关于国务院机构改革方案的决定》，组建国家市场监督管理总局，作为国务院直属机构；组建国家药品监督管理局，由国家市场监督管理总局管理，不再保留国家食品药品监督管理总局。目前机构改革工作正在抓紧进行。

期间，在国家市场监督管理总局和国家药品监督管理局"三定"方案公布前，原国家食品药品监督管理总局承担的食品、药品、医疗器械、化妆品、保健食品、婴幼儿配方乳粉、特殊医学用途配方食品的审评审批、监督检查、检验检测、稽查执法、投诉举报、信息公开等事项仍按原有规定办理；各类批件、证书、文书等暂沿用原有格式，所使用的业务印章和文本格式暂不改变、办理程序暂不改变。机构改革到位后，有关事项另行告知。

（2018-04-10）

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

National Drug Administration Issued the *Announcement on 7 Varieties of Drugs (Third Batch) Accredited by Quality & Efficacy Consistency Evaluation of Generic Drugs Including Amoxicillin Capsule*

On April 12, 2018, National Drug Administration issued the *Announcement on 7 Varieties of Drugs (Third Batch) Accredited by Quality & Efficacy Consistency Evaluation of Generic Drugs Including Amoxicillin Capsule*. Information for the package inserts, enterprise research reports and bioequivalence test data of the above varieties can be found on the Website of the Center for Drug Evaluation.

(April 12, 2018)

国家药品监督管理局发布《关于阿莫西林胶囊等7个品种规格通过仿制药质量和疗效一致性评价的公告（第三批）》

2018年4月12日，国家药品监督管理局发布《关于阿莫西林胶囊等7个品种规格通过仿制药质量和疗效一致性评价的公告（第三批）》。上述品种的说明书、企业研究报告及生物等效性试验数据信息可登录药品审评中心网站查询。（2018-04-12）

Announcement on Definition Results of the Attributes of the Fifth Batch Drug-Device Combination Products Released

To guide applicants to apply properly, on March 27, 2018, CFDA announced the Definition Results of the Attributes of the Fifth Batch Drug-Device Combination Products (Annex Omitted).

(March 27, 2018)

《关于第五批药械组合产品属性界定结果的公告》发布

为引导申请人合理申报，2018年3月27日，国家食品药品监督管理总局将第五批药械组合产品属性界定结果予以公告（附件略）。（2018-03-27）

Medical Devices

National Drug Administration Issued the *Guidelines for Technical Review of Oral Pantomography X-Ray Machine Registration*

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, National Drug Administration organized the formulation of the *Guidelines for Technical Review of Oral Pantomography X-Ray Machine Registration*, which has been released on April 16, 2018.

(April 16, 2018)

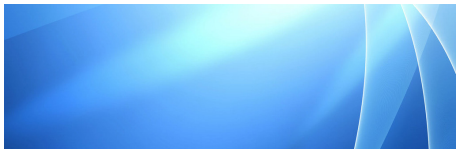
医疗器械

国家药品监督管理局发布《口腔曲面体层X射线机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《口腔曲面体层X射线机注册技术审查指导原则》，2018年4月16日发布。（2018-04-16）

Guidelines for Technical Review of Rigid Optical Endoscope (Invasive) Registration Released

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Rigid Optical Endoscope (Invasive) Registration*, which has been released on March 27, 2018. (March 27, 2018)



《硬性光学内窥镜（有创类）注册技术审查指导原则》发布

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，国家食品药品监督管理总局组织制定了《硬性光学内窥镜（有创类）注册技术审查指导原则》，于2018年3月27日发布。（2018-03-27）

Guidelines for Technical Review of Continuous Glucose Monitoring System Registration Released

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Continuous Glucose Monitoring System Registration*, which has been released on March 21, 2018.

(March 21, 2018)

《持续葡萄糖监测系统注册技术审查指导原则》发布

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，国家食品药品监督管理总局组织制定了《持续葡萄糖监测系统注册技术审查指导原则》，于2018年3月21日发布。（2018-03-21）

Guidelines for Technical Review of Mycobacterium Tuberculosis Specific Cellular Immune Response Reagent Registration Released

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Mycobacterium Tuberculosis Specific Cellular Immune Response Reagent Registration*, which has been released on March 21, 2018.

(March 21, 2018)

《结核分枝杆菌特异性细胞免疫反应检测试剂注册技术审查指导原则》发布

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，国家食品药品监督管理总局组织制定了《结核分枝杆菌特异性细胞免疫反应检测试剂注册技术审查指导原则》，于2018年3月21日发布。（2018-03-21）

Annual Reports

Annual Report for National Adverse Drug Reaction Monitoring (2017) Released

As per the *Drug Administration Law of the People's Republic of China and the Provisions for Adverse Drug Reaction Reporting and Monitoring*, in order to comprehensively reflect China's ADR monitoring in 2017, the former CFDA organized the National Center for ADR Monitoring to perform a comprehensive analysis and summary of the 1.429 million copies of ADR/ADE Reports received by the Center in 2017, as a fruition the Annual Report for National Adverse Drug Reaction Monitoring (2017) was published on April 10, 2018. which is excerpted as follows:

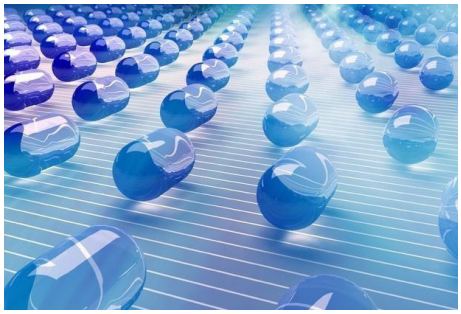
Overall Situation of Adverse Drug Reaction/Event (ADR/ADE) Reporting

1. Annual ADR/ADE reporting in 2017

In 2017, the National ADR Monitoring Network received a grand sum of 1.429 million copies of ADR/ADE Reports, with a decrease of 0.1% from 2016. From 1999 to 2017, the National ADR Monitoring Network received a total of 12.182 million copies of ADR/ADE Reports.

2. New and serious ADR/ADE reporting

In 2017, the National ADR Monitoring Network received 433,000 new and serious



ADR/ADE reports, up by 2.2% Year over Year (YOY); accounting for 30.3% of the total number of reports in 2017, which marks an increase of 0.7 percentage points from 2016. The steady growth of the proportion of new and serious ADR/ADE reports indicates a constant up-climbing of the availability of ADR reports in China.

年报

《国家药品不良反应监测年度报告（2017年）》发布

根据《中华人民共和国药品管理法》《药品不良反应报告和监测管理办法》，为全面反映2017年我国药品不良反应监测情况，原国家食品药品监督管理总局组织国家药品不良反应监测中心，对2017年全国药品不良反应监测网络收到的全部142.9万份《药品不良反应/事件报告表》情况进行全面分析汇总，形成《国家药品不良反应监测年度报告（2017年）》，于2018年4月10日发布。部分内容如下：

药品不良反应 / 事件报告总体情况

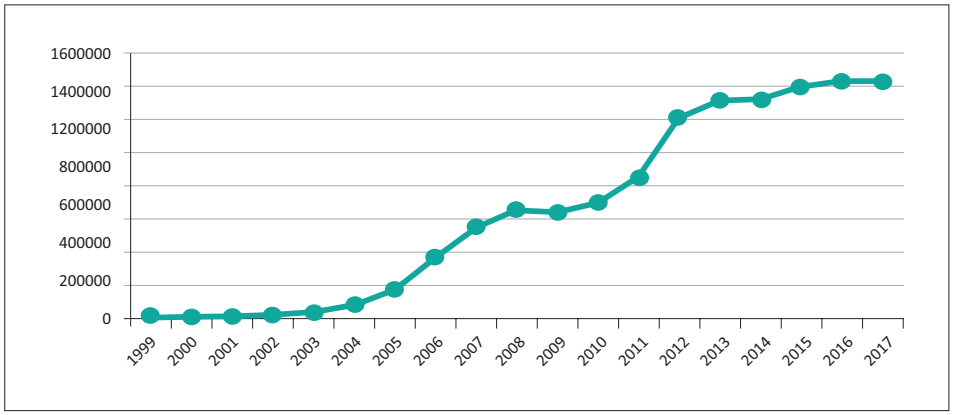
1. 2017年度药品不良反应/事件报告情况

2017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》142.9万份，较2016年降低了0.1%。1999年至2017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》1218.2万份。

2. 新的和严重药品不良反应/事件报告情况

2017年全国药品不良反应监测网络收

图. 1999年—2017年全国药品不良反应/事件报告数量增长趋势
Figure. Growth Trend of ADR/ADE Reports in China from 1999 to 2017



In 2017, the National ADR Monitoring Network received 126,000 copies of serious ADR/ADE reports, and the number of serious reports accounted for 8.8% of the total number of reports in the same period, up by 1.6 percentage points YOY.

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 1,068 in 2017, flat with that in the previous year.

4. ADR/ADE county reporting ratio

ADR/ADE county reporting ratio is an important indicator for measuring the balanced development and coverage of ADR monitoring in China. In 2017, the percentage of national ADR/ADE reports at the county level was 98.0%, up by 0.3 percentage points YOY.

5. Sources of ADR/ADE reports

Pharmaceutical manufacturers, distributors and medical institutions constitute the responsible units for ADR/ADE reporting. As per source-specific statistics of ADR/ADE reports in 2017, a lion's share of 88.0% came from medical institutions; while a share of 9.9%, 1.8%, and 0.3% came from pharmaceutical distributors, manufacturers, individuals and other sources, respectively. The situation is basically the same as the source-specific statistics of 2016.

6. Reporter occupation

In occupation-specific statistics, the composition of which being basically identical with that in 2016, doctors accounted for 56.8%, pharmacists accounted for 23.7%, nurses accounted for 15.6%, and other occupations accounted for 3.9%.

7. Patients involved in the ADR/ADE reports

In the 2017 ADR/ADE reports, the proportion of male patients and female patients was close to 0.89:1, with men slightly outnumbered by women, and this gender distribution trend was basically the same as that in 2016. Reports of pediatric patients under 14 years of age accounted for 9.9%, leveled with that in 2016; elderly patients over the age of 65 accounted for 26.0%, which is higher than 2016.

8. Drug categories involved in ADR/ADE reports

According to the statistics on the categories of suspected drugs, chemical drugs accounted for 82.8%, Chinese traditional medicines accounted for 16.1%, and biological products accounted for 1.1%, this is basically the same as that in 2016.

As per the statistics of routes of administration of drugs involved in 2017 ADR/ADE reports, 61.0% were administered by intravenous injection, 3.7% by other injections, 32.0% by oral administration, and 3.3% by other routes of administration. Compared with 2016, the

到新的和严重药品不良反应/事件报告43.3万份，较2016年增长了2.2%；新的和严重报告数量占同期报告总数的30.3%，较2016年增加了0.7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报告可利用性持续增加。

2017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12.6万份，严重报告数量占同期报告总数的8.8%，较2016年增加了1.6个百分点。

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国家药品不良反应监测工作水平的重要指标之一。2017年我国每百万人口平均报告数量为1068份，与2016年持平。

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。2017年全国药品不良反应/事件县级报告比例为98.0%，较2016年增长了0.3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。按照报告来源统计，2017年来自医疗机构的报告占88.0%，来自药品经营企业的报告占9.9%，来自药品生产企业的报告占1.8%，来自个人及其他的报告占0.3%。与2016年报告来源情况基本相同。

6. 报告人职业

按报告人职业统计，医生占56.8%，药师占23.7%，护士占15.6%，其他职业占3.9%。与2016年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

2017年药品不良反应/事件报告中，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2016年基本一致。14岁以下儿童患者的报告占9.9%，与2016年持平；65岁以上老年患者的报告占26.0%，较2016年有所升高。

8. 药品不良反应/事件报告涉及药品情况

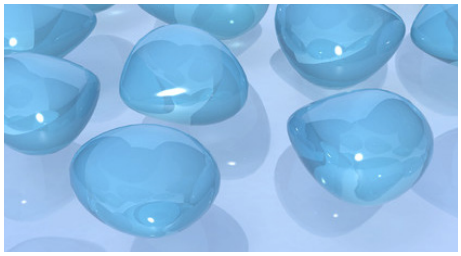
按照怀疑药品类别统计，化学药品占82.8%、中药占16.1%、生物制品占1.1%，与2016年基本一致。

按照药品给药途径统计，2017年药品不良反应/事件报告中，静脉注射给药占61.0%、其他注射给药占3.7%、口服给药占

ratio of intravenous injections increased by 1.3%.

9. Organs/systems damaged by ADRs/ADEs

In the 2017 ADR/ADE reports, the top five damaged organs/systems are: skin and its appendages (27.6%); gastrointestinal system damage (24.4%); systemic damage (11.1%), neurological impairment (9.1%) and cardiovascular system damage (4.1%). The top 5 organs/systems damaged by chemical drugs and TCMs are consistent with the overall ranking, but the top 5 organs/systems damaged by biological products are different with the overall ranking: in proper order, skin and its appendages (32.7%), systemic damage (19.7%), immune dysfunctions and infections (10.2%), gastrointestinal damage (6.5%), and nervous system damage (5.2%). (April 13, 2018)



32.0%、其他给药途径占3.3%。与2016年相比，静脉注射给药途径占比升高1.3%。

9. 药品不良反应/事件累及器官系统情况

2017年药品不良反应/事件报告中，累及器官系统排名前5位的是皮肤及其附件损害（27.6%）、胃肠损害（24.4%）、全身性损害（11.1%）、神经系统损害（9.1%）和心血管系统损害（4.1%）。化学药品、中药累及器官系统前5位排序与总体一致，生物制品累及系统前5位与总体有所不同，依次为皮肤及其附件损害（32.7%）、全身性损害（19.7%）、免疫功能紊乱和感染（10.2%）、胃肠损害（6.5%）和神经系统损害（5.2%）。 (2018-04-13)

2017 Annual Statistical Report on Food and Drug Supervision Released

On April 3, 2017, CFDA published the 2017 *Annual Statistical Report on Food and Drug Supervision*, which is excerpted as follows:

Drug registration

As for new drug review and approval, in 2017, a total of 734 applications for clinical trials of INDs have been approved, along with 20 new drug certificates plus approval numbers, 9 approval numbers; as well as 42 special applications for clinical trials in accordance with new drug application procedures.

For generic drugs, 251 clinical trial applications and 224 production applications have been approved.

For imported drugs, 316 applications for clinical trials have been approved along with 93 applications for marketing.

In 2017, CFDA approved a total of 2,158 drug supplementary applications and filed 546 applications. The food and drug administrations of all provinces (autonomous regions and municipalities) of China approved a total of 4,251 drug supplementary applications and filed 12,264 records.

In 2017, CFDA approved a total of 552 applications for production of packaging materials and containers in direct contact with drugs, 338 applications for registration renewal, and 62 supplementary applications.

Medical device registration

In 2017, China approved 5,993 and 867 initial registrations for domestic Class II and Class III medical devices, respectively; 389 and 189 initial registrations for imported (incl. from Hong Kong, Macao, and Taiwan) Class II and Class III medical devices, respectively; 7,193 and 1,616 registration renewals for domestic Class II and Class III medical devices, respectively; 1,655 and 1,631 registration renewals for imported (incl. from Hong Kong, Macao, and Taiwan) Class II and Class III medical devices, respectively; 4,584 and 489 applications for changes of licensed items for domestic Class II and Class III medical devices,

《2017年度食品药品监管统计年报》发布

2017年4月3日，国家食品药品监督管理总局发布《2017年度食品药品监管统计年报》，部分内容如下：

药品注册情况

2017年在新药审批工作中共批准新药临床734件，新药证书及批准文号20件，批准文号9件；共批准按新药申请程序申报临床申请42件。

2017年共批准仿制药临床申请251件，生产申请224件。

2017年共批准进口药品申请临床316件，上市93件。

2017年总局共批准药品补充申请2158件，备案546件。全国各省（区、市）局共批准药品补充申请4251件，备案12264件。

2017年共批准直接接触药品的包装材料和容器生产申请552件，再注册申请338件，补充申请62件。

医疗器械注册情况

2017年，全国共批准境内第二类医疗器械首次注册5993件，境内第三类医疗器械首次注册867件，进口（含港澳台）第二类医疗器械首次注册389件，进口（含港澳台）第三类医疗器械首次注册189件。批准境内第二类医疗器械延续注册7193件，境内第三类医疗器械延续注册1616件，进口（含港澳台）第二类医疗器械延续注册1655件，进口（含港澳台）第三类医疗器械延续注册1631件。境内第二类医疗器械许可事项变更4584

respectively; 555 and 591 applications for changes of licensed items for imported (incl. from Hong Kong, Macao, and Taiwan) Class II and Class III medical devices, respectively.

Registration of cosmetics

In 2017, a total of 2,537 applications for initial registration, 979 for registration renewal and 2,510 for registration change of special-purpose cosmetics have been approved; along with 12,683 applications for initial filing, 3,163 for renewal and 1,300 for change of non-special-purpose imported cosmetics.

Notes:

[1] The data in this report are sourced from the *Food and Drug Supervision and Administration Statistical Reporting System*. Unless otherwise specified, the data reporting period is from December 1, 2016 to November 30, 2017.

[2] Medical device production licensing: an enterprise producing both Class I and Class III products are counted separately as production enterprises of Class I devices and those of Class III devices, and as one in the total number of enterprises.

(April 2, 2018)

件，境内第三类医疗器械许可事项变更489件，进口（含港澳台）第二类医疗器械许可事项变更555件，进口（含港澳台）第三类医疗器械许可事项变更591件。

化妆品注册情况

2017年共批准特殊用途化妆品首次申报2537件，延续979件，变更2510件；批准进口非特殊用途化妆品首次备案12683件，延续3163件，变更1300件。

注：

[1] 本报告数据来源于《食品药品监督管理统计报表制度》。除特殊说明外，数据报告期为2016年12月1日至2017年11月30日。

[2] 医疗器械生产许可情况：既生产一类产品又生产三类产品的企业，统计时分别计为一类生产企业和三类生产企业，企业总数仅计一家。

(2018-04-02)

2017 Annual Report for Medical Device Registration Released

On March 27, 2018, CFDA issued the 2017 *Annual Report for Medical Device Registration*, which is excerpted as follows:

Medical device registration applications

In 2017, CFDA has, according to its powers and duties, accepted a total of 6,834 applications for initial registration, registration renewal, and registration change of medical devices. Compared with 2016, the number of accepted registration applications decreased by 23.4%.

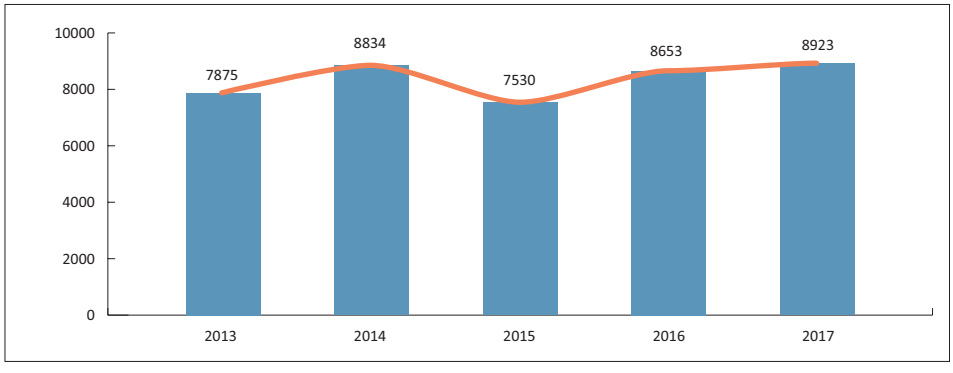
Review & approval of medical device registration

In 2017, CFDA completed technical review of a total of 8,579 medical device registration applications, down by 8.1% compared to 2016. Of these, 1,507 were for initial registration, 5,218 were for registration renewal, and 1,854 were for registration change.

In 2017, CFDA approved 8,923 applications for initial registration, registration renewal and registration change of medical devices. Compared with 2016, the total number of registration applications approved increased by 3.1%.

In 2017, CFDA has rejected a total of 223 medical device registration applications, 331

图. 2013-2017年批准医疗器械注册情况
Figure. Review & approval of medical device registration in 2013-2017



《2017年度医疗器械注册工作报告》发布

2018年3月27日，国家食品药品监督管理总局发布《2017年度医疗器械注册工作报告》。部分内容如下：

医疗器械注册申请受理情况

2017年，食品药品监管总局依职责共受理医疗器械注册、延续注册和许可事项变更申请6834项，与2016年相比注册受理项目减少23.4%。

医疗器械注册审评审批情况

2017年，食品药品监管总局共完成医疗器械注册申请技术审评8579项，与2016年相比减少8.1% 。其中，首次注册1507项，延续注册5218项，许可事项变更1854项。

2017年，食品药品监管总局共批准医疗器械注册、延续注册和许可事项变更注册项8923。与2016年相比注册批准总数量增长3.1%。

2017年，食品药品监管总局共对223项医疗器械注册申请不予注册，企业自行撤回331项。

创新医疗器械等产品审评审批情况

2017年，食品药品监管总局按照《创新医疗器械特别审批程序（试行）》，继续做

of which were voluntarily withdrawn by the enterprises.

Review & approval of innovative medical devices and other products

In 2017, CFDA sought furtherance and betterment of reviewing innovative medical devices as per the *Special Review & Approval Procedure for Innovative Medical Devices (Interim)*, and approved the marketing for some of them.

In 2017, CFDA received a total of 273 applications for special review & approval for innovative medical devices, completed review of 323 applications (including those in 2016), and determined that 63 products entered the Special Review & Approval Procedure for Innovative Medical Devices. Twelve innovative products such as branch-type aortic stent graft and delivery systems were approved for marketing. Among them, there were 4 active medical devices and 8 passive medical devices, outnumbering those of 2016 by 2 products.

Notes: The statistics period of this report is from January 1, 2017 to December 31, 2017.

(March 28, 2018)

好创新医疗器械审查工作，并批准了部分创新医疗器械产品上市。

2017年，食品药品监管总局共收到创新医疗器械特别审批申请273项，完成323项审查（含2016年申请事项），确定63个产品进入创新医疗器械特别审批通道。批准注册分支型主动脉覆膜支架及输送系统等12个创新产品上市。其中，有源医疗器械4项，无源医疗器械8项，与2016相比总数增加2项。

注：本报告的数据统计自2017年1月1日至2017年12月31日。

（2018-03-28）

2017 Drug Review Annual Report Released

On March 23, 2018, CFDA issued the *2017 Drug Review Annual Report*. Among them, the completion status of the review and approval of drug registration applications is as follows:

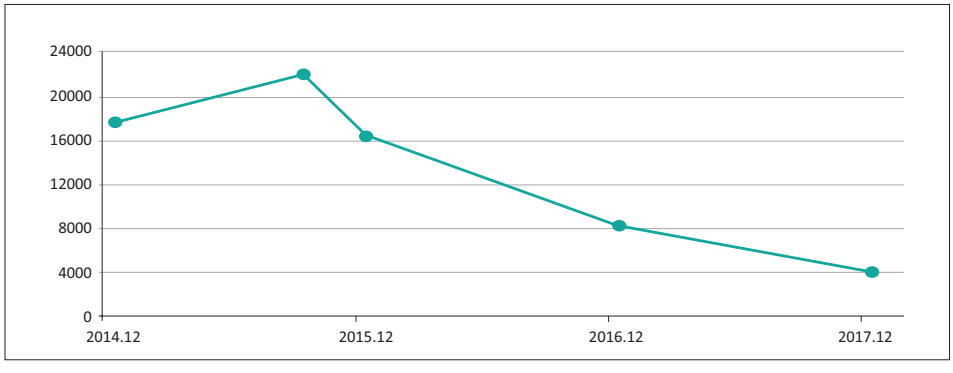
1. Approval of registration applications for marketing of drugs

In 2017, CFDA approved 394 registration applications for marketing of drugs (in terms of drug approval numbers), which can be segmented into 369 chemical drugs, 2 TCM ethnic medicines (hereinafter referred to as TCMs), and 23 biological products; 278 domestic drugs and 116 imported drugs; 28 new chemical drugs, 1 new TCM, 10 biological products, 238 chemical generic drugs, and 1 generic TCM in terms of domestic drugs; 53 varieties were included in the priority review & approval, accounting for 13.5%.

2. Completion of review & approval in 2017

Pursuant to the CFDA's *Decision on Adjusting the Administrative Review and Approval Procedures for Some Drugs* (CFDA Order No. 31), based on its original technical review function, the Center for Drug Evaluation, CFDA (hereinafter referred to as CDE) undertakes three administrative review and approval decision-making functions for drug clinical trials, drug supplementary applications, and import registration renewal. In 2017, CDE completed a total of 9,680

图1. 2014—2017年排队等待审评的注册申请数量变化情况
Figure 1. Changes in the Number of Registration Applications Pending for Review in 2014-2017



《2017年度药品审评报告》发布

2018年3月23日，国家食品药品监督管理总局发布《2017年度药品审评报告》。其中，药品注册申请审评审批完成情况如下：

1. 批准上市药品情况

2017年，总局批准上市药品394个（以药品批准文号计），其中化学药品369个，中药民族药（以下简称中药）2个，生物制品23个；国产药品278个，进口药品116个；国产药品中化学新药28个，中药新药1个，生物制品10个，化学仿制药238个，中药仿制药1个；纳入优先审评审批品种53个，占13.5%。

2. 全年审评审批完成情况

根据总局《关于调整部分药品行政审批事项审批程序的决定》（局令第31号），在原有技术审评职能的基础上，国家食品药品监督管理总局药品审评中心（以下简称药审中心）承接药物临床试验、药品补充申请和进口再注册3项行政审批决定职能。2017年，药审中心完成审评审批的注册申请共9680件（以受理号计，下同），其中完成审评的注册申请8773件，完成直接行政审批（无需技术审评，下同）的注册申请907件。排队等待审评的注册申请已由2015年9月高峰时的近22000件降至4000件（不含完成审评因申报资料缺陷等待申请人回复补充资料的注册申请），中药、化药、生物制品各类注册申请基本实现按法定时限审评审批，基本完成了国务院44号文件确定的解决药品注册申请积压的工作目标。2014—2017年排队等待审评的注册申请数量变化情况详见图1。

registration applications (according to the application number, the same below) for review & approval, wherein 8,773 are registration applications with technical review, and 907 are direct administrative review and approval (without technical review, the same below). The number of registration applications pending for review has fallen from nearly 22,000 at the peak of September 2015 to 4,000 (excluding registration applications with completed review awaiting for applicants' supplementary information due to defects in application dossiers). The review & approval of TCMs, chemical drugs, biological products and other varieties of products basically met the statutory deadlines, and the work objectives set by Document No. 44 of the State Council to solve the backlog of drug registration applications, have been basically completed. The changes in the number of registration applications pending for review in 2014-2017 are detailed in Figure 1.

Of the applications with completed review, 7,729 were registered for chemical drugs, accounting for about 88% in all.

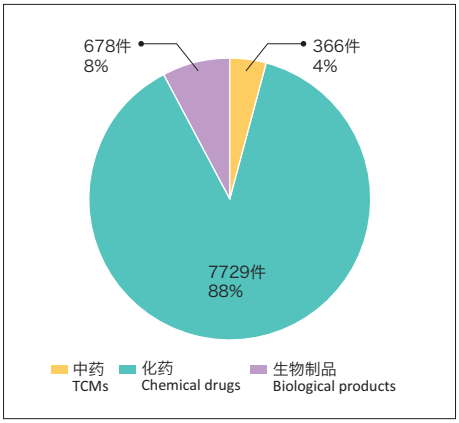
3. Completion of review for various types of registration applications

CDE completed review for 908 applications for clinical trials of Investigational New Drugs (INDs), 294 New Drug Applications (NDAs), 4,152 Abbreviated New Drug Applications (ANDAs) for marketing. 744 IND applications (involving 373 varieties) have been approved, 143 NDAs (involving 76 varieties) and 273 ANDAs (involving 123 varieties) have passed the review and are recommended for approval.

Notes: The number of varieties of chemical drugs is based on the statistical analysis of active ingredients, while the number of varieties of TCMs and biological products are all reported under the generic names of drugs.

(March 23, 2018)

图2. 2017年各类药品注册申请审评完成情况
Figure 2. Completion of Registration Review of Various Drugs in 2017

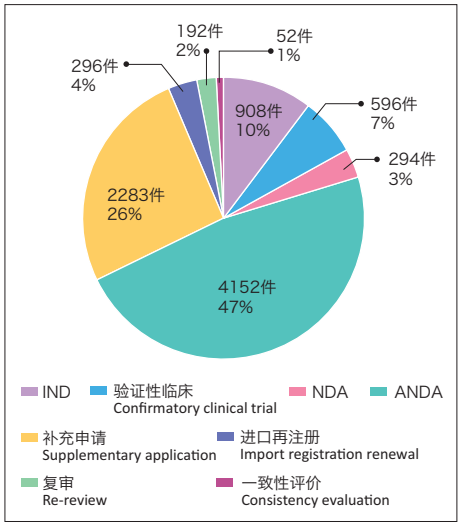


完成审评的申请中，化药注册申请为7729件，约占全部审评完成量的88%。

3. 各类注册申请审评完成情况

药审中心完成新药临床试验（IND）申请审评908件，完成新药上市申请（NDA）审评294件，完成仿制药上市申请（ANDA）审评4152件；审评通过批准IND申请744件（涉及373个品种），审评通过建议批准NDA 143件（涉及76个品种），审评通过建议批准ANDA 273件（涉及123个品种）。

图3. 2017年各类注册申请审评完成情况
Figure 3. Completion of Review for Various Types of Registration Applications in 2017



注：化药的品种数以活性成分统计，中药和生物制品的品种数均以药品通用名称统计。

(2018-03-23)

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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