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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

The 2018 Drug Review Annual Report released

On July 1, 2019, the 2018 Drug Review Annual Report was released, which is excerpted as follows:

In 2018, under the strong leadership of the National Medical Products Administration (hereinafter referred to as NMPA), the Center for Drug Evaluation (hereinafter referred to as CDE) has, pursuant to the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42, hereinafter referred to as Document No. 42); the State Council's Opinions on Reforming the Review & Approval System for Drugs and Medical Devices (State Council [2015] No. 44 (hereinafter referred to as Document No. 44), and the requirements of the Standing Committee of the State Council on April 12 and June 20, performed a series of tasks to encourage innovation in drug R&D, improve drug quality, and guarantee drug safety, effectiveness and accessibility, etc. CDE has furthered the reform of the drug review & approval system with high responsibility and sense of mission, adhered to the law-based, scientific and standardized review, to resolutely safeguard and promote public health.

I. Acceptance of drug registration applications

In 2018, CDE accepted a total of 7,336 new registration applications (counted by acceptance numbers, the same below), of which 5,574 are subject to technical review, the rest to direct administrative examination and approval (dispense with technical review, the same below). Compared with 2017, the number of registration applications requiring technical review by CDE saw a substantial increase (up by 47%) in 2018, whereof the numbers of applications for registration of TCMs, chemicals and biologicals all saw a significant increase (up by 30%, 50% and 42%, respectively).

In 2018, CDE accepted the registration applications for a total of: ---264 varieties of innovative drugs (involving 533 acceptance numbers, the number of varieties of chemical drugs is based on the statistical analysis of active ingredients, while the varieties of TCM and biological products are all counted by their generic names), up by 21% YOY, covering 239 INDs (up by 15% YOY) and 25 NDAs (up by 150% YOY) for Class 1 innovative drugs.

--- 157 varieties of Class 1 chemicals, covering 16 NDAs (up by 100% YOY) for Class 1 innovative chemical drugs.

--- 37 varieties of Class 1-6 new TCMs, covering 8 NDAs (increased 8 times than that in 2017); and 29 INDs, one of which went for Class 1 TCM innovative drugs.

--- 106 Class 1 innovative biologicals (an increase of 62% over 2017, involving a total of 123 acceptance numbers for 6 preventive biologicals and 117 therapeutic biologicals), covering 9 NDAs (involving 11 acceptance numbers, 2 for preventive biologicals and 9 for therapeutic biologicals), increased 5.5 times than that in 2017.

(I) Overall situation

Of the 7,336 new registration applications accepted by CDE, those for chemical drugs accounted for 82% (5,979) of the total. For a four-year comparison, see Figure 1 for details.

Among the 5,574 applications requiring technical review, 4,459 were for chemical drugs, accounting for 80% of all those for

《2018年度药品审评报告》发布

2019年7月1日，《2018年度药品审评报告》发布，部分内容如下：

2018年，国家药品监督管理局药品审评中心（以下简称药审中心）在国家药品监督管理局（以下简称国家局）坚强领导下，继续贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号，以下简称42号文件）和国务院《关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号，以下简称44号文件）精神，按照4月12日和6月20日国务院常务会议要求，在鼓励药物研发创新、提高药品质量、保障人民用药安全有效可及等方面开展了一系列工作，以高度的责任感和使命感持续深化药品审评审批制度改革，坚持依法依规、科学规范审评，坚决维护和促进公众健康。

一、药品注册申请受理情况

2018年，药审中心受理新注册申请共7336件（以受理号计，下同），其中需技术审评的注册申请5574件，直接行政审批（无需技术审评，下同）的注册申请1762件。与2017年相比，2018年药审中心需技术审评的注册申请任务受理量大幅增长（较2017年增长了47%），且中药、化药和生物制品各类药品注册申请任务受理量均有较大幅度增长（较2017年分别增长了30%、50%和42%）。

2018年，药审中心受理1类创新药注册申请共264个品种（涉及533件受理号，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，下同），较2017年增长了21%。其中，受理1类创新药的新药临床试验（IND）申请239个品种，较2017年增长了15%；受理1类创新药的新药上市申请（NDA）25个品种，较2017年增长了150%。

2018年，药审中心受理1类化药创新药注册申请共157个品种，其中，受理1类化药创新药NDA 16个品种，较2017年增长了100%。

2018年，药审中心受理1-6类中药新药注册申请共37个品种，其中，受理中药NDA 8个品种，较2017年增长了7倍；受理中药IND 29个品种，且有1个品种为1类中药创新药IND申请。

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technical reviews, and 300 and 815 were for TCMs and biologicals, respectively.

(II) Acceptance of domestically produced innovative drugs

CDE accepted 448 applications for the registration of domestically-produced Class 1 innovative drugs (involving 222 varieties), of which 403 were for INDs (involving 198 varieties), and 45 were for NDAs (involving 24 varieties). As per drug-specific statistics, 323 applications were for chemical drugs (involving 115 varieties), 2 for TCMs (involving 1 variety), and 123 biologicals (involving 106 varieties). The indications of innovative drugs are mainly concentrated in the field of anti-tumor and endocrine systems, and digestive systems.

(III) Imported drugs

CDE accepted 75 applications for registration of Class 5.1 imported chemical brand-name drugs (involving 50 varieties), and 85 applications for registration of imported innovative drugs (incl. 42 varieties). The indications for innovative drugs are mainly focused on anti-tumor, circulatory and digestive systems.

(VI) Acceptance of various types of registration applications

1. Chemical drugs

CDE accepted 5,979 applications for registration of chemical drugs, of which 107 were for NDAs, an increase of 43% compared with 2017; and 982 applications were for ANDAs (generic drugs), an increase of 79% compared with 2017. The details of the acceptance of registration application for various classes of chemical drugs are shown in Figure 2. The 2015-2018 acceptance of registration applications for clinical trial, marketing and consistency evaluation of chemical drugs is detailed in Figure 3.

图1 2018年各类药品注册申请受理情况与近三年比较

Figure 1 Acceptance of various drug registration applications from 2015 to 2018

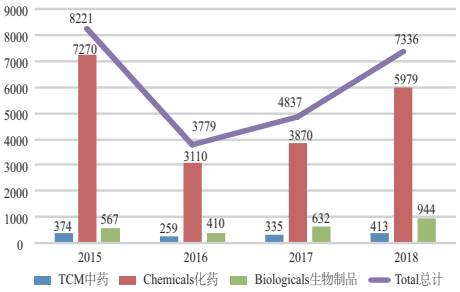
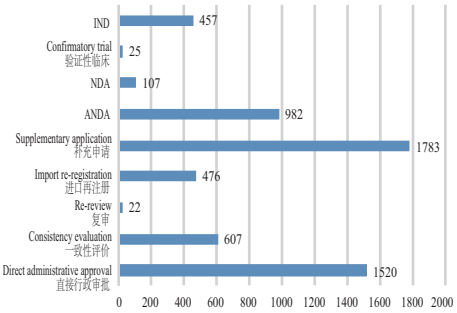


图2 2018年化药各类注册申请受理情况

Figure 2 Acceptance of registration application for various classes of chemical drugs in 2018



2. Acceptance of TCM registration applications

CDE accepted 413 TCM registration applications, covering 31 applications for

(1) Innovative chemicals

CDE accepted registration applications for 157 varieties of Class 1 innovative chemicals, covering 16 innovative NDAs (up by 100% YOY), 115 varieties of domestically produced innovative chemicals, and 42 imported ones. For such details from 2015 to 2018, see Figure 4.

(2) Indications for chemical INDs

CDE accepted 457 applications for chemical INDs, of which 325 were for domestic ones, and 132 for imported ones. The indications for domestic IND applications are mainly concentrated in the fields of anti-tumor, endocrine and digestive systems; those for imported IND applications are mainly concentrated in the fields of anti-tumor, endocrine system and circulatory system. The specific therapeutic areas are shown in Figure 5.

2018年，药审中心受理1类生物制品创新药注册申请106个品种（包括预防用生物制品6件，治疗用生物制品117件，共涉及123件受理号），较2017年增长了62%。其中，受理1类生物制品NDA 9个品种（包括预防用生物制品2件，治疗用生物制品9件，共涉及11件受理号），较2017年增长了4.5倍。

（一）总体情况

2018年，药审中心受理的7336件新注册申请中，化药注册申请受理量为5979件，占2018年全部注册申请受理量的82%，2018年各类药品注册申请受理情况与近三年比较详见图1。

需技术审评的5574件注册申请中，化药为4459件，占全部需技术审评的注册申请受理量的80%，中药和生物制品注册申请分别为300件和815件。

（二）国产创新药受理情况

药审中心受理国产1类创新药注册申请448件（涉及222个品种），其中受理临床申请403件（涉及198个品种），上市申请45件（涉及24个品种）。按药品类型统计，化药323件（涉及115个品种），中药2件（涉及1个品种），生物制品123件（涉及106个品种），创新药的适应症主要集中在抗肿瘤、内分泌系统和消化系统领域。

（三）进口药受理情况

药审中心受理5.1类化药进口原研药注册申请75件（涉及50个品种），受理1类进口创新药注册申请85件（涉及42个品种），创新药的适应症主要集中在抗肿瘤、循环系统和消化系统领域。

（四）各类注册申请受理情况

1. 化药注册申请受理情况

药审中心受理化药注册申请共5979件，其中受理化药NDA申请107件，较2017年增长了43%；受理仿制药上市申请（ANDA）982件，较2017年增长了79%。化药各类注册申请受理情况详见图2。2018年化药临床、上市和一致性评价注册申请受理情况与

图3 2018年化药临床、上市和一致性评价注册申请受理情况与近三年比较

Figure 3 2015-2018 acceptance of registration applications for clinical trial, marketing and consistency evaluation of chemical drugs

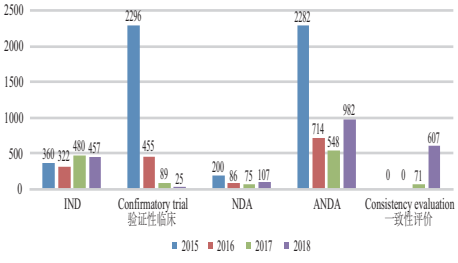


图4 2015—2018年化药创新药注册申请受理情况（以品种计）

Figure 4 Acceptance of registration applications for innovative chemicals in 2015-2018 (in terms of variety)

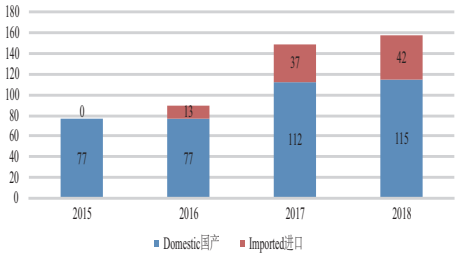


图5 2018年受理的化药IND申请治疗领域分布情况
Figure 5 Distribution of therapeutic areas for chemical IND applied and accepted in 2018

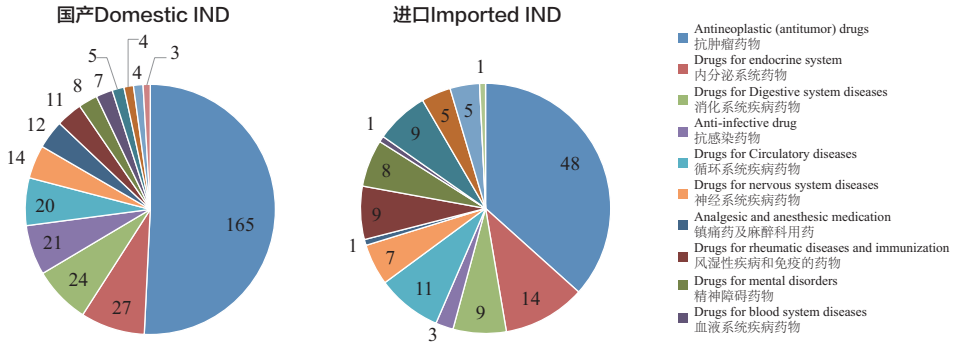


图6 2018年中药各类注册申请受理情况
Figure 6 Acceptance of various TCM registration applications in 2018

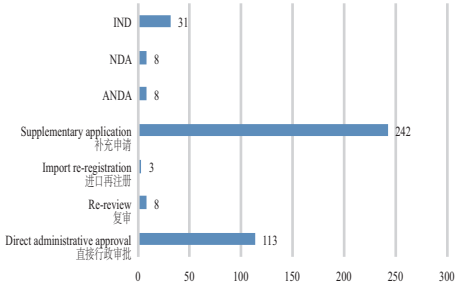
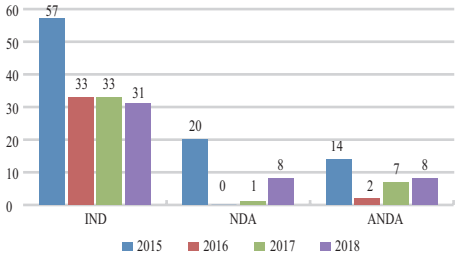


图7 2018年中药临床和上市注册申请受理情况与近三年比较
Figure 7 Acceptance of registration applications for TCM clinical trials and marketing in 2015-2018



INDs, 8 NDAs, and 8 ANDAs. The details of the acceptance of registration applications for various TCMs are shown in Figure 6. The 2015-2018 acceptance of registration applications for TCM clinical trials and marketing is detailed in Figure 7.

(1) New TCMs

CDE accepted 39 applications for registration of Class 1-6 new TCMs, covering 8 NDAs (8 varieties involved), increasing 8 times than that in 2017; 31 INDs (incl. 29 varieties), 2 of which were for Class 1 innovative TCM (involving 1 variety).

(2) Indications of TCM INDs

CDE accepted 31 applications for TCM INDs, 65% of which are with therapeutic areas mainly covering digestion, cardiovascular, respiratory and psychoneural system.

3. Biological products

CDE accepted 944 applications for registration of biological products, covering 298 INDs; and 85 NDAs, up by 70% YOY. For such details, see Figure 8. The acceptance of registration applications for clinical trials and marketing of biologicals in 2015-2018 is detailed in Figure 9.

(1) Class 1 innovative biologicals

CDE accepted 123 applications for registration of Class 1 innovative biologicals (incl. 6 prophylactic biologicals and 117 therapeutic ones), an increase of 62% over 2017, covering 11 Class 1 NDAs (incl. 2 prophylactic products and 9 for therapy, involving 9 varieties), increasing 5.5 times than that of 2017; 112 Class 1 INDs (incl. 4 prophylactic products and 108 therapeutic ones, involving 97 varieties), an increase of 51% over 2017.

(2) Indications of INDs of Class 1 innovative biologicals for therapeutic use

CDE accepted 108 IND applications for Class 1 therapeutic biological products (involving 93 varieties), 70% of which have indications mainly concentrated in the field of anti-tumor treatment, for specific therapeutic areas, see Figure 10.

II. Review & approval of drug registration applications

(I) Overview of accomplished review & approval

1. Review & approvals accomplished in 2018

As of the end of 2018, CDE had accomplished over 90% of the review & approval of registration applications for TCM,

近三年比较详见图3。

（1）创新药受理情况

药审中心受理1类化药创新药注册申请157个品种，整体较2017年略有增加，其中受理创新药NDA 16个品种，较2017年增长了一倍。2018年受理的157个化药创新药注册申请中，国产化药创新药注册申请为115个品种，进口化药创新药注册申请为42个品种，2015年至2018年创新药注册申请受理情况详见图4。

（2）化药新药临床试验申请适应症

药审中心受理化药IND申请457件，其中受理国产化药IND申请325件，受理进口IND申请132件。国产化药IND申请的适应症主要集中在抗肿瘤、内分泌系统和消化系统领域。进口IND申请的适应症主要集中在抗肿瘤、内分泌系统和循环系统领域，具体治疗领域分布详见图5。

2. 中药注册申请受理情况

药审中心受理中药注册申请413件，其中受理中药IND申请31件，受理中药NDA 8件，受理中药ANDA 8件。中药各类注册申请受理情况详见图6。2018年中药临床和上市注册申请受理情况与近三年比较详见图7。

（1）中药新药受理情况

药审中心受理1-6类中药新药注册申请39件，其中受理中药NDA 8件（涉及8个品种），较2017年增长了7倍；中药IND 31件（涉及29个品种），其中1类中药创新药IND申请有2件（涉及1个品种）。

（2）中药新药临床试验申请适应症

药审中心受理中药IND申请31件，主要治疗领域为消化、心血管、呼吸和精神神经，占全部中药IND申请的65%。

3. 生物制品注册申请受理情况

药审中心受理生物制品注册申请944件，其中受理生物制品IND申请298件；受理生物制品NDA 85件，较2017年增长了70%。生物制品各类注册申请受理情况详见图8。2018年生物制品临床和上市注册申请受理情况与近三年比较详见图9。

（1）1类生物制品创新药受理情况

药审中心受理1类生物制品创新药注册申请123件（包括预防用生物制品6件，治疗用生物制品117件），较2017年增长了62%。其中，受理1类生物制品NDA 11件（包括预防用生物制品2件，治疗用生物制品9件，共涉及9个品种），较2017年增长了4.5倍；受理1类生物制品IND 112件（包括预防用生物制品4件，治疗用生物制品108件，共涉及97个品种），较2017年增长了51%。

（2）1类治疗用生物制品创新药临床试验申请适应症

图8 2018年生物制品各类注册申请受理情况
Figure 8 Acceptance of various registration applications for biologicals in 2018

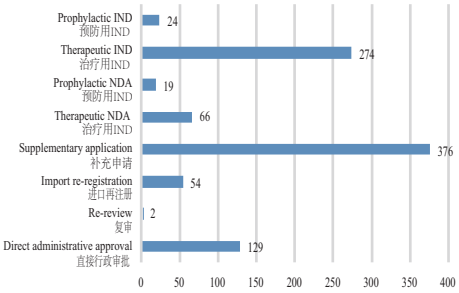
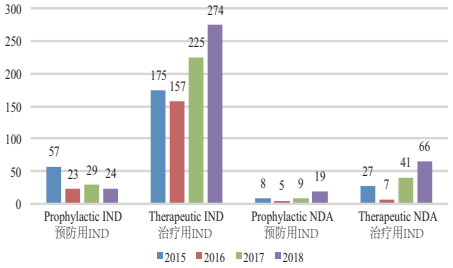


图9 2018年生物制品和上市注册申请受理情况与近三年比较
Figure 9 Acceptance of registration applications for clinical trials and marketing of biologicals in 2015-2018



chemicals and biologicals, thus basically completed the objective set forth in Doc. No. 44 requiring the completion of review & approval in 2018 within the prescribed time limit. Of the grand sum of 9,796 registration applications reviewed and approved in 2018, 7,988 were subject to technical review (incl. 4,052 administrative approval tasks requiring technical review), and 1,808 to direct administrative approval.

The number of pending registration applications has dropped from nearly 22,000 at the peak of September 2015 to 3,440 (excluding those applications whose review have been completed and are pending for the Applicants' supplementary dossiers) by the end of 2018, further consolidating the accomplishment of liquidating the backlog of registration applications as required by Doc. No. 44. The changes in the number of registration applications queued up for review & approval in 2014-2018 are shown in Figure 11.

Of the applications with completed review, 6,624 were registered for chemical drugs, accounting for about 83%. The completion status of various types of drug registration applications in 2015-2018 is detailed in Figure 12.

2. Completed category-specific reviews for registration application

In 2018, CDE completed the reviews for 1,094 IND applications, 296 NDAs, and 2,388 ANDAs. The completion of the review of various drug registration applications in 2015-2018 is detailed in Figure 13.

3. Approved reviews

In 2018, CDE reviewed and approved (in the Annual Review Report of previous years, it was stated as passed the review and recommended for approval, the same below) 947 INDs, 175 NDAs, and 1,038 ANDAs.

CDE reviewed and approved the marketing of 9 varieties of Class 1 innovative drugs, and 67 varieties of imported brand-name drugs. For details, see Annexes 1 and 2.

(II) Completion of the review of chemicals registration applications

1. Overall situation

CDE completed the review of registration applications for 6,624 chemical drugs, including 843 clinical applications (IND and confirmatory trial), 206 NDAs, and 2,353 ANDAs. See Figure 14 for details of the various registration applications for chemical drugs that have been reviewed.

2. Approved reviews

CDE completed 206 reviews of chemicals NDA, 132 (in terms of acceptance number) of which were approved, a comparison with the previous three years is shown in Figure 15. For details of various registration applications for chemical drugs with completed reviews in 2018, see Table 1.

CDE completed reviews for 603 applications for chemicals IND, 554 of which were approved, including 449 IND applications for Class 1 innovative drugs (involving 172 varieties). The numbers of IND approved for Class 1 chemical innovative drugs in 2015-2018 (in terms of variety) are shown in Figure 16.

CDE reviewed and approved the INDs of 172 varieties of innovative drugs, mostly for anti-tumor, digestive system, endocrine system and anti-infective use, accounting for 68% of the total. The distribution of indications for innovative chemicals (in terms of variety)

药审中心受理1类治疗用生物制品IND申请108件（涉及93个品种），适应症主要集中在抗肿瘤治疗领域，占全部1类治疗用生物制品IND申请的70%，具体治疗领域分布详见图10。

二、药品注册申请审评审批情况

（一）审评审批总体完成情况

1. 全年审评审批完成情况

2018年底，药审中心实现中药、化药、生物制品各类注册申请按时限审评审批率已超过90%，基本完成了44号文件确定2018年实现按规定时限审批的工作目标。全年完成审评审批的注册申请共9796件，其中完成需技术审评的注册申请7988件（包含4052件需技术审评的行政审批任务），完成直接行政审批的注册申请1808件。

2018年底排队等待审评审批的注册申请已由2015年9月高峰时的近22000件降至3440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），进一步巩固了44号文件要求解决注册申请积压的成效。2014年—2018年排队等待审评审批的注册申请数量变化情况详见图11。

完成审评的申请中，化药注册申请为6624件，约占全部审评完成量的83%。2018年各类药品注册申请审评完成情况与近三年比较详见图12。

2. 各类注册申请审评完成情况

药审中心完成IND申请审评1094件，完成NDA审评296件，完成ANDA审评2388件，2018年各类注册申请审评完成情况与近三年比较详见图13。

3. 审评通过情况

2018年，药审中心审评通过批准IND申

图10 2018年受理的1类治疗用生物制品IND申请治疗领域分布情况
Figure 10 Distribution of therapeutic areas of IND applications for Class 1 therapeutic biologicals accepted in 2018

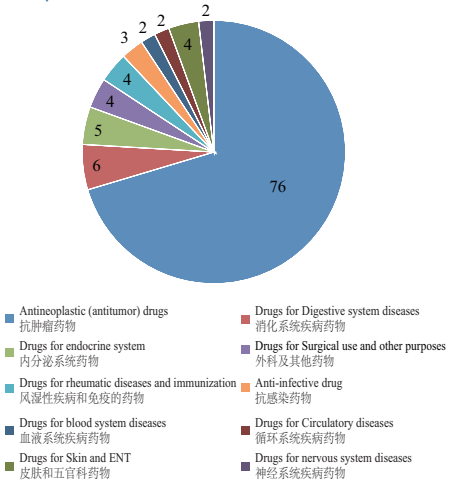


图11 2014—2018年排队等待审评审批的注册申请数量变化情况
Figure 11 Changes in the number of registration applications queued up for review & approval in 2014-2018

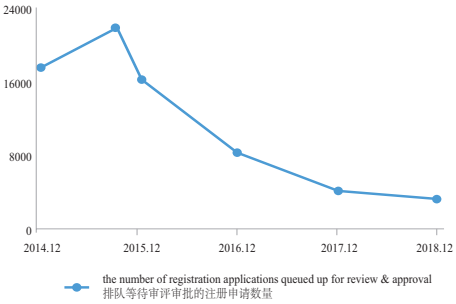


图12 2018年各类药品注册申请审评完成情况与近三年比较
Figure 12 Completion of the review of various drug registration applications in 2015-2018

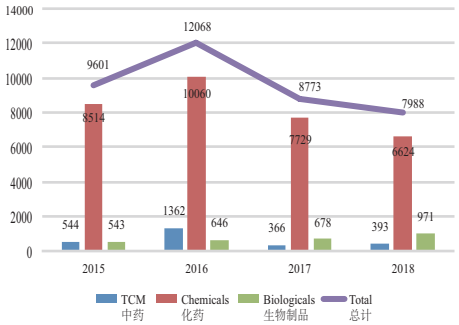
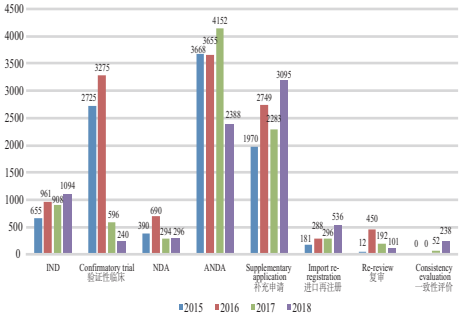


图13 2018年各类注册申请审评完成情况与近三年比较
Figure 13 Completion of the review of various drug registration applications in 2015-2018



with approved INDs is shown in Figure 17.

(III) Completion of the review of TCM registration application

1. Overall situation

CDE completed 393 reviews of TCM registration applications, covering 61 INDs, 9 NDAs, and 35 ANDAs. See Figure 18 for details of the various TCMs registration applications with completed reviews.

2. Approved reviews

CDE reviewed and approved 44 TCM IND applications; 2 TCM NDAs (involving 2 varieties: Guanhuangmu Particles, Jinrong Particles). The details of completed reviews for various TCM registration applications are shown in Table 2. The comparison of TCM IND approval and NDA approval (in terms of acceptance number) from 2015 to 2018 is shown in Figure 19.

CDE reviewed and approved 44 TCM IND applications, involving 10 indications covering cardiovascular, psychoneural, and respiratory systems, accounting for 48%. The specific therapeutic areas are shown in Figure 20.

(IV) Completion of the review of registration application for biologicals

1. Overall situation

A total of 971 applications for biologics registration were completed by CDE, covering 53 IND applications for prophylactic biological products (prophylactic IND), 377 IND applications for therapeutic biological products (therapeutic IND), 18 NDAs for prophylactic biological products (prophylactic NDA), and 63 NDAs for therapeutic biological products (therapeutic NDA).

图14 2018年完成审评的化药各类注册申请情况
Figure 14 Reviewed registration applications for various chemical drugs in 2018

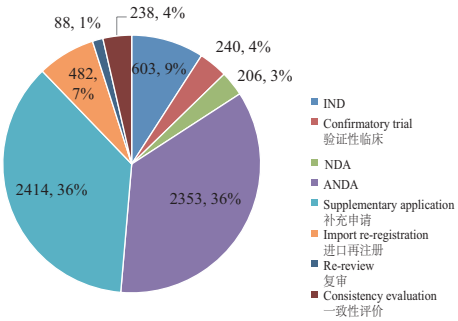


图15 2018年化药NDA通过数量与前三年比较
Figure 15 Comparison of the number of approved reviews of chemicals NDA in 2015-2018

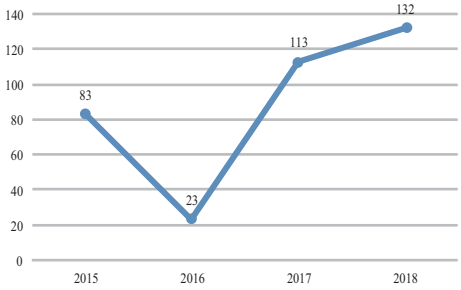


表1 2018年完成审评的化药各类注册申请具体情况
Table 1 Details of completed reviews for various registration applications of chemicals in 2018

Application type 申请类型	Completed review (counted in number) 完成审评情况（件）			
	Approved review (incl. approvals after supplementing data) 审评通过（含完善资料后通过）	Disapproved as per suggestions 建议不批准	Others 其他	Total 合计
IND	554	12	37	603
Confirmatory trial 验证性临床	130	14	96	240
NDA	132	9	65	206
ANDA	1038	115	1200	2353
Supplementary application 补充申请	1776	127	511	2414
Import re-registration 进口再注册	395	27	60	482
Consistency evaluation 一致性评价	/			238
Re-review复审	/			88
Total合计	/			6624

注：“其他”是指申请人主动申请撤回的注册申请、完成审评等待申请人补充完善申报资料的注册申请、非药审中心审评报送国家局药品注册管理司的注册申请、送国家局医疗器械技术审评中心的药械组合注册申请和关联制剂撤回的原料/辅料注册申请等，下同。
Note: "Others" refers to those registration applications which are spontaneously withdrew by the applicant, or which have gone through the review while waiting for the applicant to submit supplementary materials, or which are not submitted to the Department of Drug Registration of NMPA by CDE, or which are sent to CMDE of NPMA for the review of drug and device combination product or which are about the withdrawal of API/excipients registration of associated agents, the same as below.

图16 2018年化药创新药临床试验批准数量与前三年比较（以品种计）
Figure 16 The number of IND applications approved for chemical innovative drugs in 2015-2018 (in terms of variety)

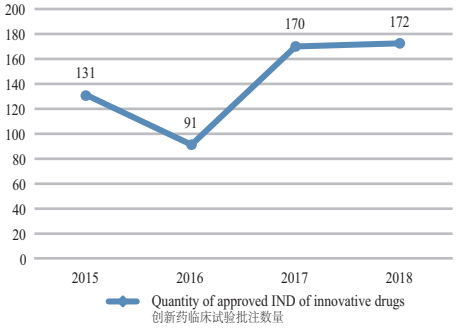


图18 2018年完成审评的中药各类注册申请情况
Figure 18 TCM registration applications with reviews completed in 2018

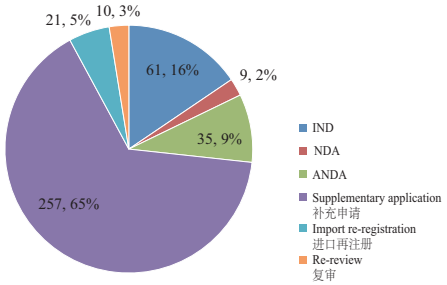
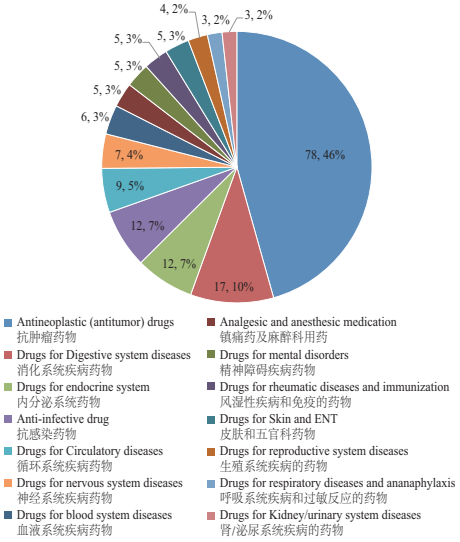


图17 2018年批准临床试验的化药创新药适应症分布（以品种计）
Figure 17 Distribution of indications for innovative chemicals (in terms of variety) with INDs approved in 2018



注：部分化药创新药有多个适应症分布在不同的适应症分组中，故上图中各适应症分组创新药品中数之和大于172个。
Note: Some of the innovative chemicals involve multiple indications and are classified into different indication groups, so therefore the sum of each indication group of INDs is more than 172 in the picture above.

See Figure 21 for details of the various registration applications for biologicals that have been reviewed.

2. Approved reviews

CDE reviewed and approved 33 prophylactic INDs, 316 therapeutic INDs; 11 prophylactic NDAs and 30 therapeutic NDAs. The details of the various registration applications for biological products completed in 2018 are shown in Table 3. The IND and NDA approval of biological products are compared with the previous three years (in terms of acceptance number) as shown in Figure 22.

CDE reviewed and approved 349 biological INDs, for details of the distribution of therapeutic areas of approved therapeutic biological INDs, see Figure 23 (omitted).

(V) Completion of administrative examination and approval tasks

In 2018, CDE completed a total of 5,860 administrative examination and approval tasks, covering 1,808 direct administrative examination and approval tasks (i.e., supplementary applications dispense with technical review) with an average time limit for examination and approval of 12.3 working days, far less than the statutory 20-day time limit for administrative examination and approval, 1,656 of which were completed within the statutory 20-day time limit, and the average completion rate within time limit was 92% in 2018. CDE completed the administrative examination and approval for 4,052 tasks with technical review (viz., IND, import re-registration and supplementary applications requiring technical review, etc.), with an average time limit of 18.6 working days, which also curtails the statutory 20-day time limit, the average completion rate within time limit was 84% in 2018. (Note:

请947件，审评通过（往年的年度审评报告中表述为“审评通过建议批准”，下同）NDA 175件，审评通过ANDA 1038件。

审评通过上市1类创新药9个品种，审评通过进口原研药67个品种，具体品种详见附件1、2。

（二）化药注册申请审评完成情况

1. 总体情况

药审中心完成审评的化药注册申请6624件，其中完成化药临床申请（IND和验证性临床）共843件，完成化药NDA 206件，完成化药ANDA 2353件。完成审评的化药各类注册申请情况详见图14。

2. 审评通过情况

药审中心完成审评的化药NDA 206件，其中审评通过132件，与前三年比较（以受理号计）详见图15，2018年完成审评的化药各类注册申请具体情况详见表1。

药审中心完成审评的化药IND申请603件，审评通过批准IND申请554件，其中批准1类创新药临床试验申请449件（涉及172个品种）。1类化药创新药临床试验批准数量与前三年比较（以品种计）详见图16。

药审中心审评通过批准创新药临床试验的172个品种中，抗肿瘤药物、消化系统药物、内分泌系统药物和抗感染药物较多，占全部创新药临床试验批准数量的68%。批准临床试验的化药创新药适应症分布（以品种计）详见图17。

（三）中药注册申请审评完成情况

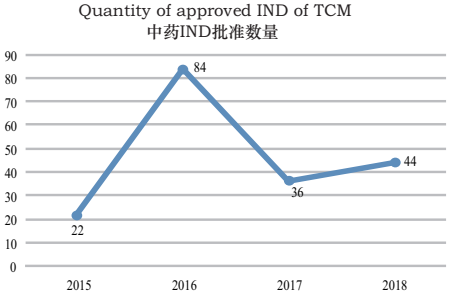
1. 总体情况

药审中心完成审评的中药注册申请393件，其中完成IND申请61件，完成NDA 9件，完成ANDA 35件。完成审评的中药各类注册申请情况详见图18。

2. 审评通过情况

药审中心审评通过批准中药IND申请44件；审评通过中药NDA 2件（涉及2个品种，关黄母颗粒、金蓉颗粒）。完成审评的中药各类注册申请具体情况详见表2，中药

图19 2018年中药IND批准和NDA通过数量与前三年比较（以受理号计）
Figure 19 TCM IND approval and NDA approval numbers (counted by acceptance numbers) in 2015-2018



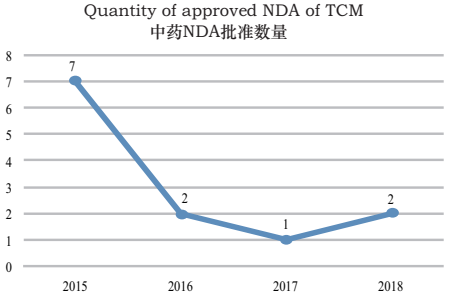


表2 2018年完成审评的中药各类注册申请具体情况
Table 2 Details of various TCM registration applications with reviews completed in 2018

Application type 申请类型	Completed review (counted in number) 完成审评情况（件）			
	Approved review (incl. approvals after supplementing data) 审评通过（含完善资料后通过）	Disapproved as per suggestions 建议不批准	Others 其他	Total 合计
IND	44	4	13	61
NDA	2	1	6	9
ANDA	0	3	32	35
Supplementary application 补充申请	139	10	108	257
Import re-registration 进口再注册	2	8	11	21
Re-review复审	/			10
Total合计	/			393

图20 2018年批准临床试验的中药适应症分布
Figure 20 Distribution of indications for TCMs with INDs approved in 2018

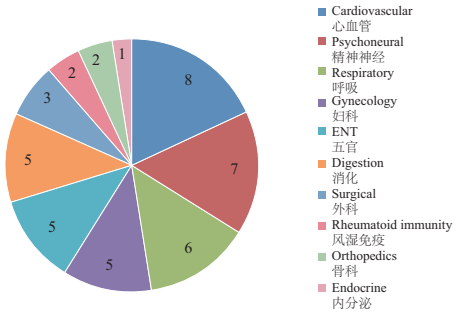


图21 2018年完成审评的生物制品各类注册申请情况Figure 21 CDE-completed reviews of various registration applications for biologicals in 2018

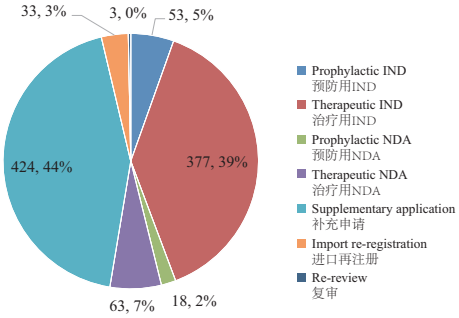
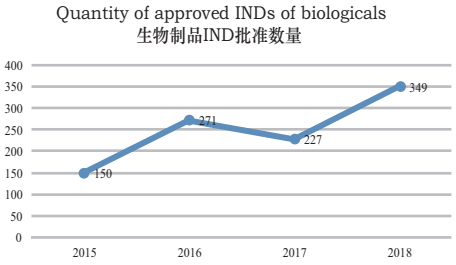
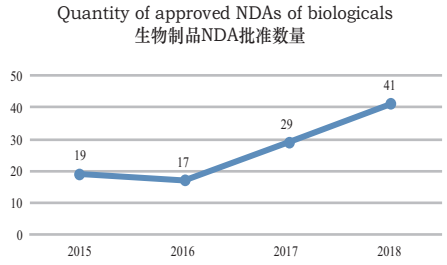


图22 2018年生物制品IND批准和NDA通过数量与前三年比较（以受理号计）
Figure 22 Comparison of the number (counted by acceptance numbers) of IND and NDA review approvals for biologicals in 2015-2018





The above-mentioned 4,052 tasks exclude those that have been accepted and reviewed prior to the joint review & approval of APIs, excipients and packaging materials and transferred to registration platform management of APIs, excipients and packaging materials.

(VI) Incorporation of prioritized review.

1. Incorporation of varieties for prioritized review

As per the Opinions on Fueling Pharmaceutical Innovation via Prioritized Review & Approval (SYJYHG [2017] No. 126) of the former China Food and Drug Administration (hereinafter referred to as the former CFDA), in 2018, CDE will have incorporated a total of 313 registration applications into prioritized review process, covering 63 applications for pediatric use and orphan diseases. Of the registration applications that were included in the prioritized review in 2018, the proportion of Synchronous Applications (which refers to 5th case in the Scope of Prioritized

IND批准和NDA通过量与前三年比较（以受理号计）详见图19。

药审中心审评通过批准临床试验的中药IND申请44件，涉及10个适应症领域，其中心血管、精神神经、呼吸较多，共占48%，具体治疗领域分布详见图20。

（四）生物制品注册申请审评完成情况

1. 总体情况

药审中心完成审评的生物制品注册申请共971件，其中完成预防用生物制品IND申请（预防用IND）53件，完成治疗用生物制品IND申请（治疗用IND）377件，完成预防用生物制品NDA（预防用NDA）18件，完成治疗用生物制品NDA（治疗用NDA）63件。完成审评的生物制品各类注册申请情况详见图21。

2. 审评通过情况

药审中心审评通过批准预防用IND 33件，批准治疗用IND 316件；审评通过预防用NDA 11件、治疗用NDA 30件。2018年完成审评的生物制品各类注册申请具体情况详见表3，生物制品IND批准和NDA通过量与前三年比较（以受理号计）详见图22。

药审中心审评通过批准生物制品IND 349件，其中批准的治疗用生物制品IND治疗领域分布详见图23（略）。

（五）行政审批任务完成情况

2018年，药审中心共完成行政审批任务5860件，其中，完成无需技术审评的直接行政审批任务（即无需技术审评的补充申请）1808件，平均审批时限为12.3个工作日，远小于法定的20日行政审批时限，其中有1656件任务在法定的20日时限内完成，全年平均按时限完成率为92%；完成需技术审评品种的行政审批任务（即临床申请、进口再注册申请、需技术审评的补充申请等）4052件，平均审批时限为18.6个工作日，小于法定的20日行政审批时限，全年平均按时限审批完成率为84%。（注：上述4052件需技术审评的行政审批任务，不包括原辅包关联审评审批实施前已受理完成审评后转原辅包登记平台管理的注册申请任务）。

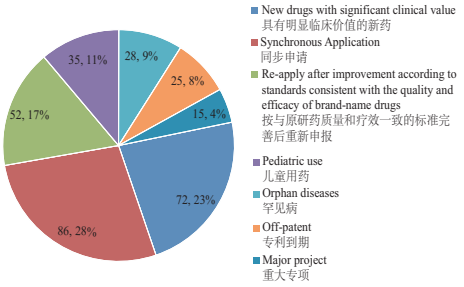
（六）优先审评纳入情况

1. 优先审评品种纳入情况

根据国家食品药品监督管理总局（以下简称原总局）《关于鼓励药品创新实行优先审评审批的意见》（食药监药化管〔2017〕126号），2018年，药审中心共将313件注册申请纳入优先审评程序，其中儿童用药和罕见病用药63件。2018年纳入优先审评的注册申请中，同步申报的品种占比最大，占比为28%，其次为具有明显临床价值的新药，占比为23%。纳入优先审评程序的注册申请情

Review & Approval (A) (CFDA No. 19), viz., drugs whose clinical trials have been simultaneously applied and approved in the European Union and the United States, or drugs that are manufactured in China with the same production line, and simultaneously applied for marketing in EU or US and have passed the on-site inspection of their drug evaluation and approval authorities) was the largest, accounting for 28%, followed by new drugs with significant clinical value, accounting for 23%. The registration applications incorporated into prioritized review process are detailed in Figure 24.

图24 纳入优先审评程序的注册申请情况
Figure 24 Registration applications incorporated into in prioritized review process



2. Completed review of varieties subject to prioritized process

In 2018, a total of 83 varieties (in generic terms) were expedited for marketing approval via prioritized review process, such as Albuvirtide for Injection, Danoprevir Sodium Oral Tablets for hepatitis C treatment, and small-molecule angiogenesis inhibitor Fruquintinib Capsules for the treatment of advanced colorectal carcinoma, and other innovative drugs independently researched and developed in China, the list of specific varieties is shown in Annex 3.

表3 2018年完成审评的生物制品各类注册申请具体情况
Table 3 Details of completed reviews for various types of registration applications for biological products in 2018

Application type 申请类型	Completed review (counted in number) 完成审评情况（件）			
	Approved review (incl. approvals after supplementing data) 审评通过（含完善资料后通过）	Disapproved as per suggestions 建议不批准	Others 其他	Total 合计
Prophylactic IND 预防用IND	33	3	17	53
Therapeutic IND 治疗用IND	316	14	47	377
Prophylactic NDA 预防用NDA	11	1	6	18
Therapeutic NDA 治疗用NDA	30	1	32	63
Supplementary application 补充申请	271	7	146	424
Import re-registration 进口再注册	23	1	9	33
Re-review复审	/			3
Total合计	/			971

(VII) Communication and exchanges (omitted)

III. Encouraging innovation and safeguarding medication safety for the public (omitted)

IV. Programs and progresses (omitted)

V. Key objectives for 2019 (omitted)

(July, 01, 2019)

况详见图24。

2. 优先审评品种审评完成情况

2018年，共有83个品种通过优先审评程序得以加快批准上市（以通用名计算），如自主研发的注射用艾博韦泰、口服丙肝治疗用新药达诺瑞韦钠片、治疗晚期结直肠癌的小分子血管生成抑制剂呋喹替尼胶囊等药品，具体品种名单详见附件3。

（七）沟通交流情况（略）

三、鼓励创新与保障公众用药情况（略）

四、主要工作措施及进展情况（略）

五、2019年重点工作安排（略）

(2019-07-01)

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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