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China Food and Drug Administration issued the "Notice on Good Food and Drug Administration during Institutional Reform"

On March 22, 2013, China Food and Drug Administration issued the "Notice on Good Food and Drug Administration during Institutional Reform", which reads as follows:

According to the State Council's Institutional Reform & Function Transition Program, adopted at the first session of the 12th National People's Congress, the responsibilities of the former State Food and Drug Administration (SFDA) have all been integrated into the newly formed China Food and Drug Administration (CFDA). At present, the relevant institutional reforms are well underway.

In the meantime, the various types of review and approval, inspection and testing, certification and examination, audit and law enforcement and other affairs assumed by the former SFDA for pharmaceuticals, medical devices, cosmetics, health food and catering industry food safety supervision, shall be handled in accordance with the original regulations. All kinds of approval documents, certificates and other files shall follow their original formats for the time being, the same applies to all business seals, text formats and processing procedures. The safety supervision over food production and circulation shall be conducted according to the original channels, for the time being, prior to the completion of work over-handing. (March 22, 2013)

国家食品药品监督管理总局发布《关于做好机构改革期间食品药品监管有关工作的公告》

2013年3月22日，国家食品药品监督管理总局发布《关于做好机构改革期间食品药品监管有关工作的公告》，内容如下：

根据十二届全国人大一次会议通过的国务院机构改革和职能转变方案，原国家食品药品监督管理局的职责已经全部整合到新组建的国家食品药品监督管理总局。目前，有关机构改革工作正在抓紧进行。

在此期间，原国家食品药品监督管理局承担的药品、医疗器械、化妆品、保健食品和餐饮环节食品安全监管各类审评审批、检验检测、认证检查、稽查执法等事项仍按原有规定办理。各类批件、证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。有关食品生产流通环节的安全监管，在交接工作完成前，暂仍按原渠道进行。

（2013-03-22）

SFDA released the 2012 Annual Report for National Adverse Drug Reaction Monitoring (according to CFDA website)

On March 14, 2013, the State Food and Drug Administration released the 2012 Annual Report for National Adverse Drug Reaction Monitoring (according to CFDA website), which notified the 2012 ADR Monitoring status from four aspects including the progress on ADR monitor, the situation of adverse drug reaction/ event reporting, data analysis and medication safety tips, and risk control measures.(according to CFDA website).

In 2012, the State Food and Drug Administration has vigorously promoted the implementation of the newly revised "Provisions for Adverse Drug Reaction Reporting and Monitoring", urging drug manufacturers, distributors and medical institutions to establish ADR reporting and monitoring system, and perform the responsibility of monitoring and reporting. At the same time, the systematic construction of ADR monitoring institutions at grassroots levels has been strengthened, the trainings on monitoring institutions at all levels have been reinforced, and their investigation, analysis and evaluation

国家食品药品监督管理局发布2012年药品不良反应监测年度报告

2013年3月14日，国家食品药品监管局发布2012年药品不良反应监测年度报告，从药品不良反应监测工作进展、药品不良反应/事件报告情况、数据分析及用药安全提示、药品风险控制等四个方面通报了2012年药品不良反应监测情况。

2012年，国家食品药品监督管理局大力推动新修订的《药品不良反应报告和监测管理办法》的贯彻实施，督促药品生产、经营企业和医疗机构建立药品不良反应报告和监测制度，履行监测和报告责任。同时，加强基层药品不良反应监测机构体系建设，加强对各级监测机构的培训，提高调查、分析和评价能力。2012年，新建成的国家药品不良反应监测系统全面

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capabilities have been greatly enhanced. In 2012, the newly established National ADR Monitoring System has come into service, the reports are more standardized and time-efficient, the quality of reporting is improved, the capacity for early warning, statistics and analysis and the data analysis capabilities of all levels of ADR Monitoring institutions are greatly enhanced, so that early detection and early control of drug safety events are ensured.

In 2012, the National ADR Monitoring Network has received a total of 1.20 million reports of ADRs / events, of which new and serious ADR / event amounted to 240,000, accounting for 20% of the total number of reports for the same period. The timeliness and the quality of reporting has been improved, the 30-day reporting ratio of general cases is up to 83.08%, a 3.2% increase over that of 2011; and the 15-day reporting ratio of severe cases is 80.2%, a 3.5% increase compared to that of 2011. Medical institutions remain to be the main body of the ADR reporting, accounting for 74.8% of the reports. The reporting ratio of drug manufacturers and distributors is also increased to some extent.

In category-specific statistics of 2012 ADR reporting, chemical drugs accounted for 81.6%, TCM 17.1%, and biological products 1.3%. In dosage form-specific statistics, injections accounted for 56.7%, oral formulations 39.5%, and other agents 3.8%. In chemical drugs, the number of anti-infective cases holds the first place, accounting for 48.8%. The statistical analysis has shown that: 1. the number of reports of anti-infective cases continued to top the list, but its proportion in the overall reports continued to decline, reflecting that the use of anti-infectives has been preliminarily controlled, but improper use still exists; 2. the number of cephalosporin ADR reports ranked first in anti-infectives ADR reports, whose serious adverse reaction is mainly manifested as allergy. Since the causes of allergy are rather complicated, it is recommended that manufacturers should carry out research deeply in this field; 3. Concerning the high safety risks of intravenous injections, medical institutions should strengthen the regulation thereof; and particular patients should eliminate their psychological dependence on injections; 4. TCM-western compound formulations are prone to be used as pure TCM formulations by the patients, neglecting their ingredients of chemical drugs, and there have been many inappropriate phenomena such as overdose and repeated use of drugs with identical ingredients, so tips should be provided to pay attention to the potential risks of these drugs in clinical use. Besides, it is also found in the 2012 Adverse Drug Reaction Monitoring that the clustering of ADR signals of individual varieties are correlated to drug quality, so the pharmaceutical manufacturers should be notified to attach great importance to the production process management of sterile drugs; the safety status of national essential drugs remains to be stable.

In 2012, according to ADR Monitoring and the corresponding analysis and evaluation, SFDA adopted related management measures for drugs found with potential safety risks. Firstly, SFDA published drug safety alerts, releasing a total of 8 "ADR Information Bulletins reporting drug safety information for 9 varieties (categories), and 12 "Pharmacovigilance Newsletter", reporting safety information for more than 60 drugs; secondly, SFDA modified the insert sheets for 15 varieties/ categories including Biyanning (Rhinitis) Capsule (particles, granules), Baofukang suppositories (gel, foam agent), pioglitazone, Orlistat, misoprostol etc., strengthened pharmaceutical risk warning; Thirdly, regarding the problems found in ADR Monitoring, SFDA timely interviewed a total of 11 related pharmaceutical manufacturers, held 13 corporate communication meetings,

投入使用，报告更规范、更快捷，报告质量也得到提高，预警、统计和分析功能大大加强，极大地提高了各级药品不良反应监测机构的数据分析能力，确保了药品安全事件早发现、早控制。

2012年，国家药品不良反应监测网络共收到药品不良反应/事件报告120万余份。其中，新的和严重的药品不良反应/事件报告24万份，占同期报告总数的20%。报告的及时性和报告质量得到提高，一般病例30日内报告比例达到83.08%，比2011年提高3.2%；严重病例15日内报告比例达到80.2%，比2011年提高3.5%。医疗机构依然是药品不良反应报告的主体，占报告的74.8%。药品生产经营企业的报告比例有所提高。

2012年药品不良反应报告按照药品类别统计，化学药占81.6%、中药占17.1%、生物制品占1.3%。按照药品剂型统计，注射剂占56.7%，口服制剂占39.5%，其他制剂占3.8%。化学药中，抗感染药的例次数仍居首位，占48.8%。通过统计分析提示，一是抗感染药病例报告数量仍居首位，但在总体报告中所占比例持续下降，反映抗感染药物的使用得到了初步控制，但不合理使用现象仍然存在；二是抗感染药中报告数量排名首位的是头孢菌素，其严重不良反应以过敏为主，引起头孢菌素过敏反应的原因较为复杂，建议生产企业深入开展研究；三是静脉注射给药安全风险较高，医疗机构要加强对注射剂使用的监管，部分患者应改变对注射剂的心理依赖；四是中西药复方制剂易被患者当作纯中药制剂使用，忽视其中所含化学药成份，使用中存在超剂量给药、含相同成份药品重复使用等不合理现象，提示应注意该类药物在临床使用过程中的潜在风险。同时，2012年不良反应监测也发现个别品种不良事件信号聚集与药品质量相关，提示药品生产企业应高度重视无菌药品的生产环节管理；国家基本药物安全状况平稳。

2012年，根据药品不良反应监测情况，国家食品药品监管局在分析评估的基础上，对发现存在安全性隐患的药品采取了相关管理措施。一是发布药品安全警示信息，全年共发布《药品不良反应信息通报》8期，通报了9个（类）药品安全性信息。发布《药物警戒快讯》12期，报道了60余条药品安全性信息；二是修改了鼻炎宁胶囊（颗粒、冲剂）、保妇康栓（凝胶、泡沫剂）、吡格列酮、奥利司他、米索前列醇等15个/类药品说明书，强化药品风险警示；三是针对药品不良反应监测中发现的问题，及时约谈相关药品生产企业，全年共约谈企业11次，召开

and required manufacturers to take risk management plans such as recall and voluntary suspension of production and sales.

In 2012, with the joint efforts of all levels of drug administration departments, health departments, and ADR monitoring institutions, as well as the active support and help from medical institutions, drug manufacturers and distributors and all social circles, ADR monitoring has achieved the planned goals, and played an important role in ensuring drug safety for the public.

(March 14, 2013)

企业沟通会13次，要求生产企业采取召回及主动暂停生产销售等风险控制措施。

2012年，药品不良反应监测工作通过各级药监和卫生部门，以及各级药品不良反应监测部门的共同努力，在医疗机构、药品生产经营企业和社会各界的积极支持帮助下，完成了工作目标，为保证公众用药安全发挥了十分重要的作用。（2013年3月14日）

SFDA released alert on medication risk of Chinese-Western compound Zhenju Jiangya Tablets

Recently, the State Food and Drug Administration issued the 52th Adverse Drug Reaction Information Bulletin, and released alert on medication risk of Chinese-Western compound Zhenju Jiangya (ZJ) Tablets.

From January 1, 2012 to December 31, 2012, the database of National Center for ADR Monitoring has recorded a total of 443 cases reporting adverse reactions of ZJ. The information analysis of the case report database has shown that ZJ adverse reactions are mainly related to its chemical drug ingredients, and serious adverse reactions become more frequent in the combination therapy. The adverse reactions of the chemical components of ZJ tablets are likely to be ignored in clinical application, thereby increasing medication risks.

According to the information analysis of the case report database and related safety risk factor analysis, SFDA recommends that:

Before administering ZJ tablets, the majority of the medical staff and patients should carefully read the package insert and fully understand the medication risks of ZJ, and learn more in detail about the patient's medical history and medication history, to avoid or reduce the occurrence of adverse reactions. If the patients have adverse reactions in the medication process, they should timely seek medical treatment and perform drug withdrawal, if necessary, under the guidance of a doctor.

Related manufacturing enterprises should improve the safety information in the package insert, add or revise warnings, notes of adverse reactions, precautions, contraindications, special population medication, drug interactions and other contents; meanwhile they should promote the publicity of ADR monitoring and rational clinical use of drugs, and take effective measures to reduce medication risks.

(2013-03-05)

国家食品药品监督管理局提醒关注中西药复方制剂珍菊降压片用药风险

日前，国家食品药品监督管理局发布第52期《药品不良反应信息通报》，提示关注中西药复方制剂珍菊降压片的用药风险。

2012年1月1日至12月31日，国家药品不良反应监测中心病例报告数据库中有关珍菊降压片的不良反应病例报告共计443例。病例报告数据库信息分析提示，珍菊降压片的不良反应主要与其化药成分有关，联合用药时严重不良反应病例的比例增加，在临床使用中易忽略化药成分的不良反应，增加用药风险。

国家食品药品监督管理局建议：广大医务人员及患者在使用珍菊降压片前，应仔细阅读药品说明书，充分了解珍菊降压片的用药风险，并详细了解患者疾病史及用药史，避免或减少不良反应的发生。患者在服药过程中如发生不良反应需及时就诊，如需停药，应在医生指导下停药。

相关生产企业应尽快完善药品说明书的安全性信息，增加或修订警示语、不良反应、注意事项、禁忌、特殊人群用药及药物相互作用等项内容；同时应加强药品不良反应监测和临床合理用药的宣传，采取有效措施，降低用药风险。（2013-03-05）

SFDA revised the insert sheet of citalopram and related preparations

On February 28, 2013, the State Food and Drug Administration decided to revise the insert sheet of citalopram and related preparations according to the adverse reaction monitoring results, to control the corresponding medication risks. The precautions, dosage and administration, contraindications, adverse reactions and related entries of the insert sheets of citalopram are required to be revised in accordance with the requirements, while the other contents should be consistent with the originally approved ones.

The State Food and Drug Administration requires the food and drug administration departments of all provinces (autonomous regions and municipalities) to inform the pharmaceutical manufacturers within the administrative area to act accordingly and promptly notify the revised contents to relevant medical institutions, pharmaceutical distributors and other units, active track the safety information of drug clinical application, and collect the adverse reactions and report in a timely manner. (2013-02-28)

国家食品药品监督管理局修订西酞普兰及相关制剂说明书

根据不良反应监测结果，为控制药品使用风险，2013年2月28日，国家食品药品监督管理局决定对西酞普兰及相关制剂说明书进行修订。要求西酞普兰及相关制剂说明书警示语、用法用量、禁忌、不良反应等项目内容按照要求进行修订，说明书其他内容应当与原批准内容一致。

药品生产企业应将修订的内容及时通知相关医疗机构、药品经营企业等单位，并主动跟踪药品临床应用的安全性情况，按规定收集不良反应并及时报告。（2013-02-28）

Center for Drug Evaluation, SFDA released the "2012 China Annual Drug Evaluation Report"

On February 28, 2013, Center for Drug Evaluation, SFDA released the "2012 China Annual Drug Evaluation Report". The Report shows that SFDA's strategy of encouraging innovation & rational allocation of resources has achieved initial success, antitumor drugs such as BMS-817378 have been approved for clinical trials simultaneously with overseas procedures and the gap of the home & abroad marketing time of imported drugs with important clinical value has also been significantly shortened.

In 2012, Center for Drug Evaluation, SFDA (CDE) has, in accordance with the laws of drug R&D, actively adjusted the review strategy, attached equal importance to innovation encouragement and risk control, and encouraged innovation and R&D to promote the research and development of generic drugs that are urgently needed in clinical application. At the same time, CDE further strengthened information disclosure to accept social supervision. For capacity building, CDE introduced evaluation mechanisms that evaluate work efficiency with quantitative indicators and data, developed and improved the management system and review process to build a professional review system framework.

From the perspective of acceptance and review of 2012 drug registration applications, the review waiting time for application of clinical trials of innovative drugs is slightly shortened and basically maintained at about 4 months; the waiting time for post-marketed supplementary application has also reduced from 5 months at the beginning of 2012 to3 months by the end of 2012. Review time (including waiting time) for domestic applications for clinical trials of chemical new drugs in 2012 is generally controlled within 8 months (72%), the majority (45%) is 6 to 7 months, 11% is within 5 months, while 15% is more than 9 months (most of them are for applications of compound varieties). As for therapeutic areas, antineoplastic agents enjoy the shortest time. From the perspective of professional review time, pharmacy review time is significantly shortened: for clinical trial varieties that have been reviewed in 2012, the average review time was 7 months before the establishment of pharmacy review templates and annual reporting system in May 2012, after that the pharmacy review time gradually reduced to 4-5 months by the end of the year. To encourage domestic applicants to carry out globally synchronized R & D, CDE accelerated the review for such applications, such as BMS-817378 and HS-25 which have been approved for clinical trials simultaneously with overseas procedures.

Some original developed imported drugs play an important to solve our unmet clinical needs and provide the latest therapeutic methods. CDE is highly concerned about the review of imported drugs that are much-needed in domestic clinical application, to enable our people to have access as soon as possible to the latest drugs in the world. Through rational allocation of review resources, CDE made efforts to shorten the time-to-market gap at home and abroad of imported drugs with important clinical value. For instance, in 2012, the approval time for the import and marketing of Sunitinib Malate Capsules (new indications), Crizotinib Capsules, Rilpivirine Tablets, Ticagrelor Tablets, etc. was only 1 year later than US FDA approval.

In 2012, after CDE review, China has approved new drugs in a number of important therapeutic areas, such as: in the field of anti-AIDS drugs, Rilpivirine Tablet was approved; thereby AIDS patients in China have a global synchronized access to the latest treatment. In the field of pediatric medication, Caffeine Citrate Injection was approved for the treatment of potentially crippling and fatal apnea of premature children, this drug is the only effective treatment for now. In the field of cancer treatment, Crizotinib Capsules, which has landmark significance, was approved for targeted therapy for

国家食品药品监管局药品审评中心发布《2012年度中国药品审评报告》

2013年2月28日，国家食品药品监管局药品审评中心发布《2012年度中国药品审评报告》。报告显示，国家食品药品监管局鼓励创新、合理配置审评资源的策略初见成效，抗肿瘤药物麦他替尼氨丁三醇片等已经做到与国外同步批准临床，一些具有重要临床价值的进口药品国内外上市时间的差距也显著缩短。

2012年，国家食品药品监管局药品审评中心按照药物研发规律，积极调整审评策略，充分发挥鼓励创新和控制风险并重的作用，鼓励创新研发，促进临床短缺的仿制药研发。同时，进一步加强信息公开力度，接受社会监督。为提高自身能力，药品审评中心引入评估机制，以定量的指标和数据来评估药品审评中心的工作效率，并制定和完善了管理制度和审评流程，构建专业化审评制度体系框架。

从2012年药品注册申请受理与审评情况看，创新药临床试验申请的审评等待时间略有缩短并基本维持在4个月左右；上市后补充申请的等待时间也从2012年初的5个月，降至2012年底的3个月。2012年国内申请人提出的化药新药临床试验申请，大部分审评用时（包括等待时间）在8个月以内（72%），以6~7个月居多（45%），5个月以内占11%，用时超过9个月的品种（15%）多数为复方申请。从治疗领域看，抗肿瘤药物所用时间最短。从专业审评用时看，药学审评用时有明显缩短，2012年完成审评的临床试验品种中，在2012年5月推出药学审评模版和年度报告制度之前，平均审评用时为7个月，此后药学审评用时逐步缩短，至年底用时为4～5个月。为鼓励国内申请人开展全球同步研发，国家食品药品监管局药品审评中心加快了此类申请的审评速度，如麦他替尼氨丁三醇片和海泽麦布片，已经做到与国外同步批准临床。

一些原研进口药品对于解决我国未被满足临床需求，提供最新治疗手段发挥着重要作用。药品审评中心关注国内临床亟需的进口药品审评，以使我国公众尽快用到全球最新的药品。通过合理配置审评资源，努力缩短具有重要临床价值的进口药品国内外上市时间的差距。如2012年批准进口上市的苹果酸舒尼替尼胶囊（新适应

anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer. In the field of orphan diseases, the domestic Decitabine injection was approved to provide a new option for the treatment of rare disease of myelodysplastic syndrome (MDS). In Geriatric field, Indacaterol Maleate Powder for Inhalation was approved for the treatment of asthma or chronic obstructive pulmonary disease (COPD), and has facilitated the patients' drug administering. The review for Memantine Hydrochloride Oral Solution, which is the first domestically developed for effective treatment of Alzheimer's disease (Senile Dementia). In the field of anti-infective drugs, Tigecycline Injection was approved, the localization of which is an important drug reserve for our response to the above-mentioned resistant bacterial infections. For the protection of this antibiotic resource, the review has clearly defined the application scope in the insert sheets in order to prevent clinical drug abuse. In the field of Rheumatism Immunity, Febuxostat Tablets was approved to provide gout patients with a new therapeutic approach with better efficacy, safety and tolerance. In the past few years, CDE has encouraged and supported the R&D of Freon-alternative propellant, in 2012, the domestic Freon substitute Ciclesonide Aerosol was marketed, which manifests our concrete action to fulfill the International Covenant of "Montreal Protocol on Ozone Depleting Substances". In the field of biological products, recombinant human coagulation factor IX injection was approved to provide a specific therapy for China's hemophilia B patients.

The report also shows that, in 2012, CDE accepted a total of 6919 (counted by acceptance number) applications for new drug registration. Compared with the previous years, the 2012 acceptance number for chemicals is slightly elevated, that of TCM drugs is slightly decreased, while that of biological products is basically the same as the previous years. China's policy to encourage innovation has been initially embodied in the drug application structure. The acceptance number of 1.1 class innovative drugs has been increased from 42 in 2009 to 78 in 2012. In recent three years, an average of 7-8 class 1.1 new drugs were marketed each year.

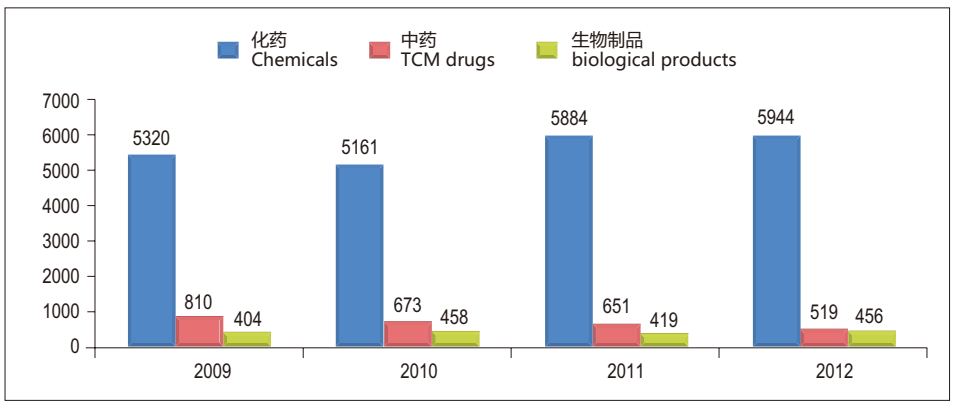
The report also shows that the registration application for generic drugs (4-6 class) has gradually returned to rational. In 2007, there were 20,000 applications, while in 2012, there were only 1852. But the phenomenon of repeat R & D and application of generics is still serious, and the insufficient industrialization of generic drug R & D remains a prominent problem.

2012 Application acceptance and review status

In 2012, CDE accepted a total of 6919 (counted by acceptance number) applications for new drug registration. A comparison is made with the accepted review tasks of previous years, which is shown in Figure 1.

Figure 1 shows that the overall acceptance number of each year fluctuated between 6500-7000, a slight increase is seen in the past two years. In 2012, the acceptance number of chemicals is slightly elevated,

图1. 2009—2012年各年度受理审评任务情况
Figure 1. 2009-2012 Annual accepted review tasks



症）、克唑替尼胶囊、利匹韦林片、替格瑞洛片等，与美国FDA批准上市时间仅间隔一年。

2012年，经过药品审评中心的审评，我国批准多个重要治疗领域药品，如：抗艾滋病药物领域，批准了利匹韦林片，使我国艾滋病患者与全球同步获得最新治疗手段。儿童用药领域，批准了用于治疗可能致残和致命的早产儿呼吸暂停症的枸橼酸咖啡因注射液，此药是目前唯一的有效治疗药物。肿瘤治疗领域，批准了具有里程碑意义的克唑替尼胶囊，针对间变性淋巴瘤激酶（ALK）阳性的非小细胞肺癌发挥靶向治疗作用。罕见病领域，批准了国产的注射用地西他滨，为罕见病骨髓增生异常综合症（MDS）的治疗提供了新选择。老年病领域，批准了马来酸茚达特罗吸入粉雾剂，用于治疗哮喘或慢性阻塞性肺病（COPD）患者，方便了患者用药。完成了盐酸美金刚口服溶液的审评，该药是首个国产的、治疗阿尔兹海默症（老年痴呆症）的有效药物。抗感染领域，批准了注射用替加环素。本品的国产化可作为我国应对上述耐药细菌感染的重要药品储备。为保护好这一抗生素资源，审评对说明书使用范围进行了明确界定，以防止临床滥用。风湿免疫领域，批准了非布司他片，为痛风患者提供了一个有效性更好，安全性也能较好耐受的新的治疗手段。过去的几年中，药品审评中心对替代氟利昂的抛射剂一直给予鼓励和支持，2012年已批准了国产氟利昂替代产品环索奈德气雾剂上市，这是对我国履行《关于消耗臭氧层物质的蒙特利尔议定书》国际公约的具体行动。生物制品领域，批准了注射用重组人凝血因子IX，为我国乙型血友病患者提供了特异性治疗用药物。

报告还显示，2012年，药品审评中心全年受理新注册申请6919个（以受理号计）。与既往年度受理审评任务比较，2012年化药受理量略有升高，中药受理量小幅下降，生物制品基本持平。国家鼓励创新的政策在药品申报结构上开始初步显现。创新药1.1类由2009年的42个受理项目，增加到2012年的78个受理项目。最近三年，每年平均有7到8个1.1类的新药上市。

报告也显示，仿制药(4-6类)注册申请逐渐回归理性。2007年有2万个申报件，到2012年则为1852个。但仿制药重复研发、重复申报现象依然严重，当前仿制药研发中工业化能力不足问题突出。

2012年受理与审评情况

2012年，药品审评中心全年受理新注

while that of TCM drugs declined slightly, and that of biological products is basically flat. In recent years, the acceptance number of chemicals basically maintained at 80-85% of the total acceptance number each year.

In 2012, the CDE completed and submitted to SFDA 4941 review tasks for approval, among which 3323 were approved, and 1618 were not approved. Of the CDE accepted review tasks, about 2000 were not completed, mainly concentrated in the chemicals.

As of the end of 2012, SFDA has approved the following drugs (excluding supplementary applications).

表1：2012年批准的药品情况
Table 1: 2012 drug approvals

注册分类 Registration Classification	新药 New Drugs	改剂型 Changed Dosage Forms	仿制药 Generic Drugs	进口药 Imported Drugs	小计 Sub-total
化学药品 Chemicals	103	13	336	80	532
中药 TCM Drugs	21	14	2	/	37
生物制品 Biological Products	29	17	46		
合计 Total	615				

Note: Counted by acceptance number (similarly hereinafter).
注：以受理号计（下同）。

表2：2012年药物临床研究批准情况
Table 2: 2012 clinical study approvals

注册分类 Registration Classification	临床实验 Clinical Trials	生物等效性试验 Bioequivalence Trials	小计 Sub-total
化学药品 Chemicals	425	178	603
中药 TCM Drugs	37	2	39
生物制品 Biological Products	62	/	62
合计 Total	704		

The tables below reflect the annual acceptance and review data of chemicals, TCM drugs and biological products, respectively.

(A) 2012 chemical drug registration application and review status

1. Acceptance status of new chemical drug applications

Table 3 shows that, in recent years, 1.1 class drug applications basically maintained around 70, while those for class 3 new drugs saw an annual increase of nearly 100, the country's policy to encourage innovation has seen initial achievement in the drug application structure.

In 2011, CDE has implemented the CDE Review Task Management Practice in accordance with international practice to perform six-channel management of review tasks, the following data are all mined through the review channels.

In 2012, there have been 5944 applications for new chemicals counted by acceptance number. Among which investigational

表3: 各类注册申请申报数量情况
Table 3: Application numbers of various registrations

年Year	2009	2010	2011	2012
1.1类新药 1.1 class new drugs	42	69	79	78
其他3类以上新药 Other new drugs above class 3	625	718	793	942
4-6类 4-6 classes	1314	1358	1806	1852
国际多中心 International multicenter	157	150	179	138
进口药 Imported drugs	365	410	459	442

册申请6919个（以受理号计）。与既往年度受理审评任务的比较情况见图1。

图1显示，各年度总体受理量在6500～7000个之间波动，其中近两年略有增加。2012年，化药受理量略有升高，中药受理量小幅下降，生物制品基本持平。几年来，化药的受理量基本保持在各年度受理总量的80%至85%。

2012年，药品审评中心完成审评并呈送国家食品药品监督管理局审批的审评任务4941个，其中批准3323个，不批准1618个。2012年药品审评中心受理量和完成量比较相差约2000个，主要集中在化学药品。

截止到2012年底，国家食品药品监督管理局已批准情况见表1、2（不包括补充申请）。

以下，分别为本年度化药、中药和生物制品的年度受理和审评数据。

（一）2012年化药受理和审评情况

1．化药新申请的受理情况（表3）

表3表明，近年来1.1类申报量基本维持在70个上下，3类新药每年增加近百个，国家鼓励创新的政策在药品申报结构上开始初步显现。

2011年，药品审评中心开始按照国际惯例，实施《药品审评中心审评任务管理规范》，对审评任务实施六个通道管理，以下数据均按审评通道进行统计（图2）。

2012年，化药新申请以受理号计共5944个。其中新药临床试验申请（IND）包括注册分类1、注册分类2和国际多中心临床试验申请；验证性临床为注册分类3和4的临床试验申请；新药生产上市申请（NDA）为完成临床试验后的生产上市申请；仿制及改剂型申请（ANDA）为注册分类5和6生物等效试验申请和生产上市申请；补充申请系已上市产品的变更申请（其中，以补充申请形式提交的创新药Ⅱ、Ⅲ期临床试验申请，已纳入IND统计）。

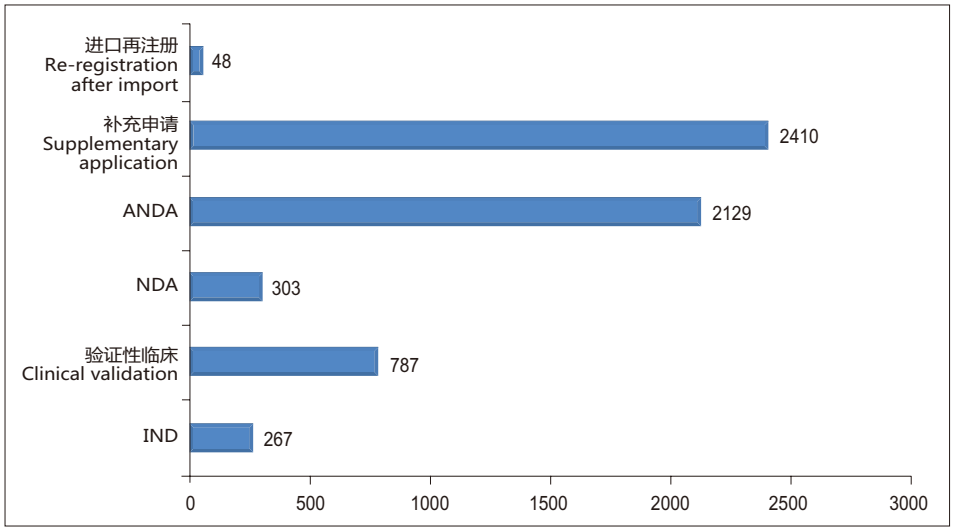
2. IND申请的治疗领域构成（图3）

无论国际多中心临床试验申请还是国内IND申请，比例最大的均为肿瘤治疗领域药物。2012年受理的国内IND肿瘤治疗领域药物中，替尼类（酪氨酸激酶抑制剂）占总申报量的64.7%，与2011年比例基本持平。

3．仿制药重复申报的情况（图4）

图4显示，2012年新申报的ANDA申请共2095个（按受理号计，不包括辅料）。已有批准文号20个以上的药品，仍有1272个申请，占2012年全年ANDA申报量的

图2. 2012年化药受理情况
Figure 2. 2012 chemical drug application acceptance



60.7%，已有批准文号10个以内的ANDA申请仅占其总申报量的20.6%。此数据显示，仿制药重复研发、重复申报现象依然严重。

另外，根据2012年“举手发言”品种试点情况（详见《中国通用名药发展研究报告》第11页），当前仿制药研发中工业化能力不足问题突出，在试点品种中，国家食品药品监督管理局发文后6个月内仅有三分之一的企业提出生产现场检查。

4．审评完成情况

2012年药品审评中心完成化药审评5461个（以受理号计，未计申请人主动撤回的284个申请），具体情况见表4。

化药审评结束并送国家食品药品监督管理局审批的4016个品种中，不批准结论占32%，总体不批准率已连续三年保持在30%左右。

new drug (IND) application included the registration class 1 , 2 and Golbel Clinical Trials clinical trial applications; clinical validation are for registration class 3 and 4 clinical trial applications; new drug applications (NDA) are for production and marketing applications after the completion of clinical trials; Abbreviated New Drug Application (ANDA) for registration class 5 and 6 Up for bioequivalence test application and production & marketing application of generics and change the dosage forms; the Supplementary Application for alteration applications of marketed products (among which, the applications for Phase II & III clinical trials of innovative drugs submitted in supplementary applications have been included in the IND statistics).

2. The treatment areas under IND application

Regardless of Golbel Clinical Trials clinical trial application or domestic IND application, the largest proportion of applications is concentrated in drugs for cancer treatment. Among the applications for domestic IND cancer treatment drugs in 2012, the -tinib (tyrosine kinase inhibitor) class applications accounted for 64.7% of the total, which is essentially flat with the 2011 ratio.

3. Repeated applications status of generics

Figure 4 shows that in 2012, there have been

图3. 2012年化药IND申请的构成
Figure 3. Structure of 2012 chemical IND applications

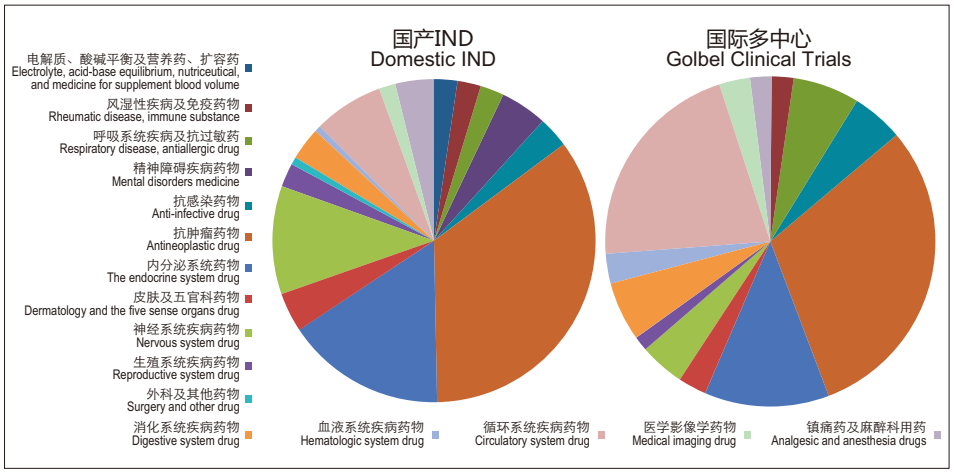
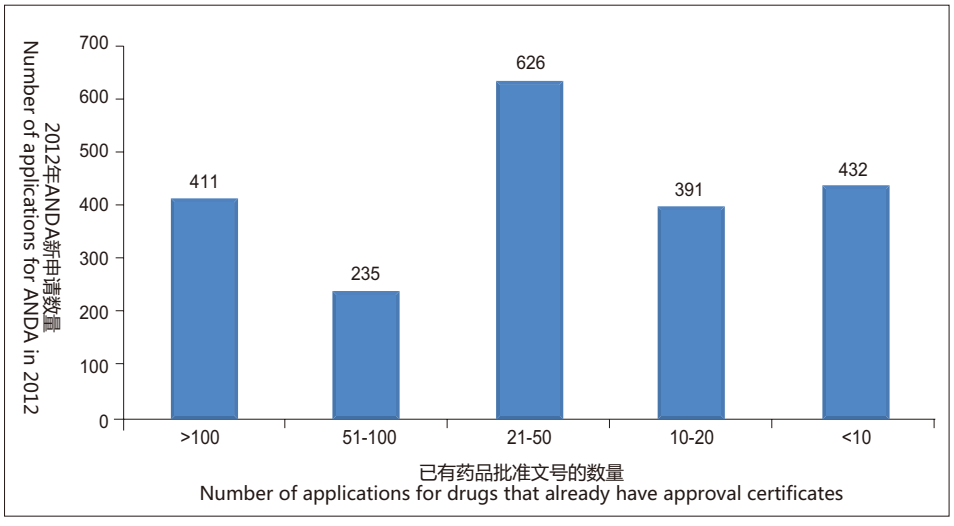


图4. 2012年已有批准文号的ANDA申请
Figure 4. ANDA Applications for drugs with approval certificates in 2012



a total of 2095 new ANDA applications (counted by acceptance number, not including excipients). There are still 1,272 applications for drugs with more than 20 approval certificate numbers, accounting for 60.7% of the 2012 annual ANDA application numbers; while ANDA applications for drugs with less than 10 approval certificate numbers accounted for only 20.6% of the total applications. This data shows that repeated R&D and applications of generic remains serious.

In addition, according to 2012 pilot of "Raise Hand and Speak out" varieties (see "Chinese Generic Drug Development Research Report" on page 11), the inadequate capacity for industrialization of generic drug R&D remains a prominent problem, in the pilot varieties, the National Bureau issued a document within, only one-third of the companies proposed production site inspection within six months after SFDA Notice.

4. Review completion status

In 2012, CDE completed the reviews for 5461 chemicals applications (counted by accepted numbers, excluding 284 applications withdrawn by the applicants), which is specified in the table below.

Of the 4016 varieties of chemicals whose applications have been reviewed and submitted for SFDA approval, 32% are not approved, the overall disapproval rate has maintained at about 30% for three consecutive years.

Figure 5 shows that the completed review tasks for four channels of IND, clinical Validation, NDA, supplementary application have all increased in 2012 than as in 2011, while the completed ANDA review tasks in 2012 and 2011 were essentially flat.

5. Review time limit status

Table 5 shows that, in 2012, the CDE has been all out to secure the review for clinical trial applications of innovative drugs, and slightly reduced the review waiting time, which is basically maintained at about 4 months; and the waiting time for supplementary application after marketing is also reduced from 5 months in early 2012 to 3 months by the end of 2012; However, ANDA wait time is extended from 14 months in early 2012 to 24 months in late 2012. At the same time, the review waiting time for NDA and clinical trial validation application has also been extended.

5.1 Time limits status for clinical drug clinical trial applications

Review time (including waiting time) for domestic applications for clinical trials of chemical new drugs in 2012 is generally controlled within 8 months (72%), the majority (45%) is 6 to 7 months, 11% is within 5 months, while 15% is more than nine months (most of them are for applications of compound varieties). As for therapeutic areas, antineoplastic agents enjoy the shortest time. From the perspective of professional review time, pharmacy review

图5显示，IND、验证性临床、NDA、补充申请四个通道2012年的完成量均较2011年有所增加，2012年ANDA的完成量与2011年基本持平。

5. 审评时限情况

表5显示，2012年，举药品审评中心之力，力保创新药临床试验申请的审评，使审评等待时间略有缩短并基本维持在4个月左右；上市后补充申请的等待时间也从2012年初的5个月，降至2012年底的3个月；但是，ANDA的等待时间从年初的14个月延长至年底的24个月。同时，NDA和验证性临床试验申请的等待审评时间也有所延长。

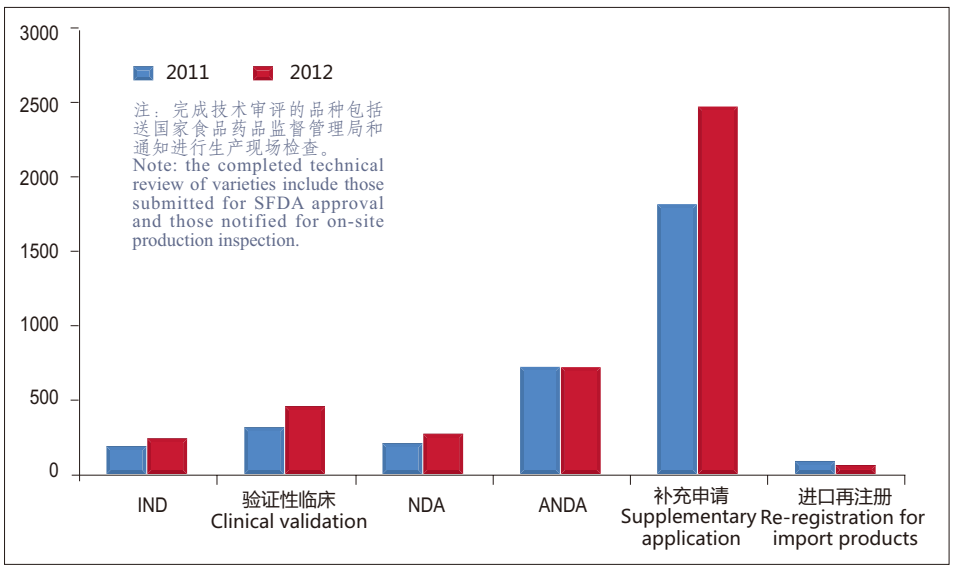
5.1 化药临床试验申请时限情况（表6）

2012年国内申请人提出的化药IND申请，大部分审评用时（包括等待时间）在8个月以内（72%），以6～7个月居多（45%），5个月以内占11%，用时超过9个月的品种（15%）多数为复方申请。从

表4: 2012年化药审评完成情况
Table 4: 2012 Chemicals review completion status

	批准 Approved	不批准 Not Approved	书面发补 Written Requirements for Supplementary Application	现场检查 Onsite Inspection
IND	202	14	55	/
验证性临床 Clinical Validation	354	99	304	/
NDA	165	27	182	81
ANDA	479	225	340	20
补充申请 Supplementary Application	1473	923	347	101
进口再注册 Re-registration for Import Products	50	5	15	/
合计 Total	2723	1293	1243	202

图5. 2011年与2012年各通道完成技术审评情况比较
Figure 5. A comparison of technical reviews completed via various channels in 2011 and 2012



time is significantly shortened: for clinical trial varieties that have been reviewed in 2012, the average review time was 7 months before the establishment of pharmacy review templates and annual reporting system in May 2012, after that the pharmacy review time gradually reduced to 4-5 months by the end of the year. To encourage domestic applicants to carry out globally synchronized R & D, CDE accelerated the review for such applications, such as BMS-817378 and HS-25 which have been approved for clinical trials simultaneously with overseas procedures. CDE's strategy of innovation incentive and rational allocation of review resources has achieved initial success.

5.2 A comparison of the approval time for marketing of imported drugs at home and abroad

Some original developed imported drugs play an important to solve our unmet clinical needs and provide the latest therapeutic methods. CDE is highly concerned about the review of imported drugs that are much-needed in domestic clinical application, to enable our people to have access as soon as possible to the latest drugs in the world. Through rational allocation of review resources, CDE made efforts to shorten the time-to-market gap at home and abroad of imported drugs with important clinical value. For instance, in 2012, the approval time for the import and marketing of Sunitinib Malate Capsules (new indications), Crizotinib Capsules, Rilpivirine Tablets, Ticagrelor Tablets, etc. was only 1 year later than FDA approval.

(B) 2012 TCM drug application acceptance and review status

1. New application acceptance status

There have been 519 new TCM drug applications (counted by acceptance numbers).

2. Review completion status

In 2012, CDE has accomplished the review for 726 TCM drugs (counted by acceptance numbers, without taking into account the 72 applicant withdrawals), specifically as follows.

3. Review time limits status

Currently, the waiting time for review of TCM drugs is not a major problem.

(C) 2012 Acceptance and review of biological products

1. New application acceptance status

There have been 456 new applications for Biological products (counted by acceptance

治疗领域看，抗肿瘤药物所用时间最短。从专业审评用时看，药学审评用时有明显缩短，2012年完成审评的IND品种中，在2012年5月推出药学审评模版和年度报告制度之前，平均审评用时为7个月，此后药学审评用时逐步缩短，至年底用时为4～5个月。为鼓励国内申请人开展全球同步研发，加快此类申请的审评速度，如麦他替尼氨丁三醇片和海泽麦布片，已经做到与国外同步批准临床。中心鼓励创新、合理

表5: 化药各审评通道启动审评情况
Table 5: Launch of review for chemical drugs by each review channel

	2012.1		2012.12	
序列 Sequence	进药审中心时间 CDE acceptance	等待时间（月） waiting time (months)	进药审中心时间 CDE acceptance	等待时间（月） waiting time (months)
IND	2011.5	6	2012.8	4
验证性临床 Clinical validation	2010.12	12	2011.8	15
NDA	2011.1	11	2011.11	12
ANDA	2010.10	14	2010.12	24
补充申请 Supplementary application	2011.7	5	2012.8	3
进口再注册 Re-registration for import products	2011.9	4	2012.6	5

表6: 各主要治疗领域临床试验申请审评时限情况
Table 6: Review time limits for clinical trial applications in major therapeutic areas

适应症* Indications	所占比例（%） Percentage (%)	平均用时（月） Average Time (Month)	最短用时（月） Shortest Time (Month)
抗肿瘤 Antitumor	32%	6.1	4.2
内分泌 Endocrine	17%	6.7	5.8
精神神经 Psychoneurosis	15%	7.3	5.8
消化 Digestion	13%	7.6	5.6

注：*比例小的治疗领域未逐一列出；表中数据源于本年度国内的47个化合物IND申请。
Note: * therapeutic areas with small proportions are not listed in detail; the data in the table derived from the IND applications of 47 domestic compounds.

图6. 2012年中药受理情况
Figure 6. 2012 TCM drug application acceptance and review status

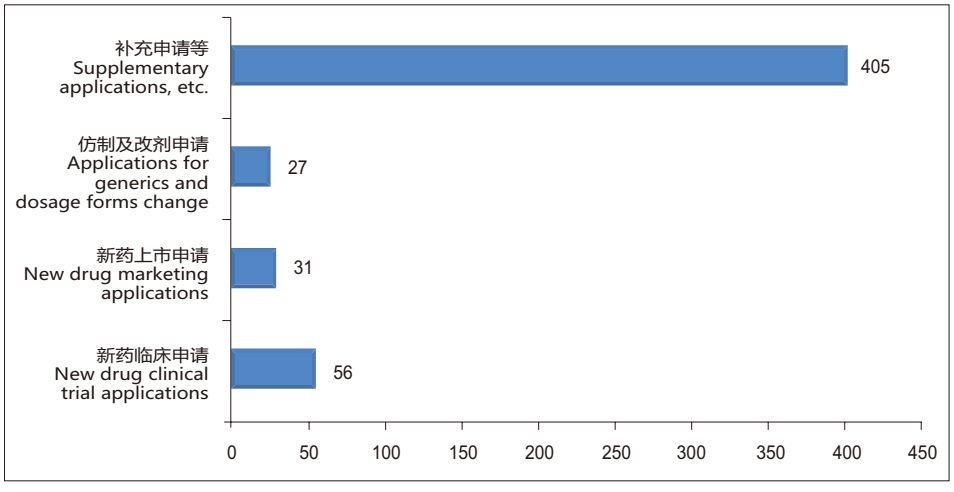
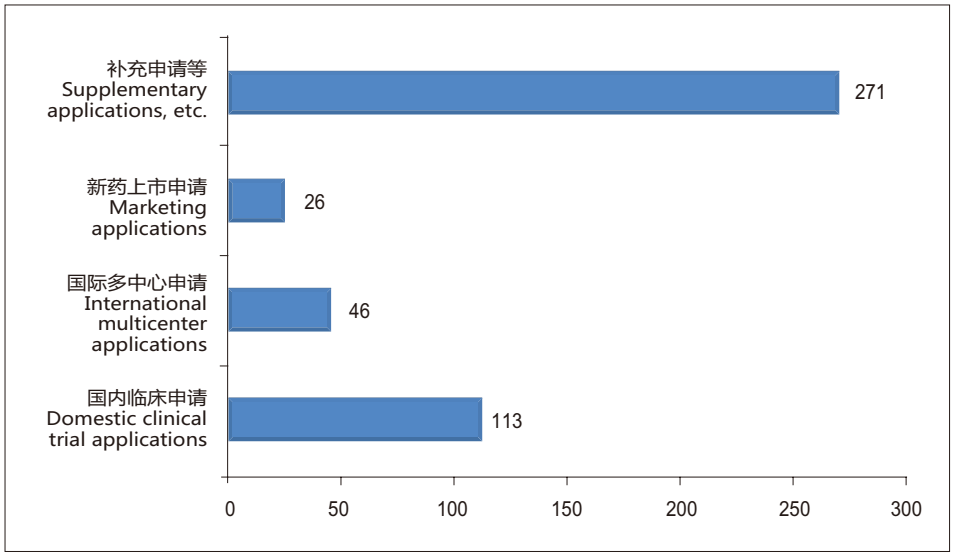


表7: 2012年中药审评完成情况
Table 7: 2012 Completed TCM drug reviews

	批准 Approved	不批准 Not approved	书面发补 Written requirements for supplementary application	现场检查 Onsite inspection
新药临床申请 New drug clinical trial applications	32	39	28	/
新药上市申请 New drug marketing applications	19	17	45	10
仿制及改剂申请 Applications for generics and dosage forms change	12	41	6	3
补充申请等 Supplementary applications, etc	230	174	70	/
合计 Total	293	271	149	13

图7. 2012年生物制品受理情况
Figure 7. 2012 CDE acceptance of biological products applications



配置审评资源的策略已初见成效。

5.2 化药进口国内外批准上市时间比较

一些原研进口药品对于解决我国未被满足临床需求，提供最新治疗手段发挥着重要作用。药品审评中心关注国内临床亟需的进口药品审评，以使我国公众尽快用到全球最新的药品。通过合理配置审评资源，努力缩短具有重要临床价值的进口药品国内外上市时间的差距。如2012年批准进口上市的苹果酸舒尼替尼胶囊（新适应症）、克唑替尼胶囊、利匹韦林片、替格瑞洛片等，与美国FDA批准上市时间仅间隔一年。

（二）2012年中药受理和审评情况

1. 新申请的受理情况

中药新申请共519个（以受理号计）（图6）。

2. 审评完成情况

2012年药品审评中心完成中药审评726个（以受理号计，未计申请人主动撤回的72个），具体情况见表7。

3. 审评时限情况

目前中药审评排队等待时间不是主要矛盾。

（三）2012年生物制品受理和审评情况

1. 新申请受理情况

生物制品新申请共456个（以受理号计）（图7）。

2. 审评完成情况

2012年药品审评中心完成生物制品审评533个（以受理号计，未计申请人主动撤回的45个），具体情况见表8。

3. 审评时限情况

生物制品审评的时限压力仍然很大。

(2013-02-28)

《2012年度中国药品审评报告》全文：http://www.cde.org.cn

number).

2. Review completion status

In 2012, CDE completed the review for 533 biological products (counted by acceptance numbers, without taking into account the 45 applicant withdrawals), which are specified in the table as follows.

3. Review time limits status

The pressure for review time limits of biological products remains high.

(2013-02-28)

For full text of "2012 China Drug Evaluation Report", see http://www.cde.org.cn

表8: 2012年生物制品审评完成情况
Table 8: 2012 Completed reviews of biological products

	批准 Approved	不批准 not approved	书面发补 written requirements for supplementary application	现场检查 onsite inspection
国内临床申请 Domestic clinical trial applications	45	16	60	/
国际多中心申请 International multicenter applications	26	1	19	/
上市申请 Marketing applications	47	10	22	6
补充申请等 Supplementary applications, etc.	189	27	48	17
合计 Total	307	54	149	23

China's 2012 pharmaceutical output grew by 21.7%

Recently, the statistics released by National Development and Reform Commission has shown that in 2012, the output value of China's pharmaceutical industry, foreign trade, economic efficiency and completed investment continued to maintain a steady growth with a stable overall development trend.

As of the end of 2012, China's pharmaceutical industry enjoys a total asset of 1.6408 trillion yuan, with an annual growth of 18.4%; and an output value of 1.8255 trillion yuan, with an annual growth of 21.7%. Among which chemical APIs amounted 330.5 billion yuan, with an annual growth of 16.6%; chemical preparations of 508.9 billion yuan, with an annual growth of 24.7%; Chinese Herbal Medicine 102 billion yuan, with an annual increase of 26.4%; proprietary Chinese medicines 413.6 billion yuan, with an annual growth of 21.3%; biological and biochemical drugs 185.3 billion yuan, with an annual growth of 20.5%; medical devices 157.3 billion yuan, with an annual growth of 20.6%. Over the same period, the pharmaceutical industry's industrial added value increased 14.5%, higher than the industry average growth rate by 4.5 percent.

In 2012, the pharmaceutical industry realized a main business income of 1.795 trillion yuan, with an annual growth of 20.1%; a total profit of 183.3 billion yuan, with an annual growth of 20.4%, which continued to maintain at a higher level. Among which, TCM slices, chemical preparations enjoyed faster growth rates of 27.5% and 25.3% respectively; the growth rates of chemical raw materials, proprietary Chinese medicines, biochemical and biological drugs are slightly lower: 15.9%, 16.9% and 14.3% respectively. Over the same period, the pharmaceutical industry's sales income margin is approximately 10.2%, which is generally the same as that of last year.

During the same period, due to the impact of the decline in demand in Europe and the United States, and the elevated import thresholds in some countries, and other factors, the growth rate of import and export of pharmaceutical industry dropped greatly, and the annual total import and export volume reached $ 81 billion, with an annual growth of 10.5%. Among them, exports amounted to $ 47.6 billion, with an annual growth of 6.9%; imports amounted to $ 33.4 billion, with an annual growth of 15.9%.

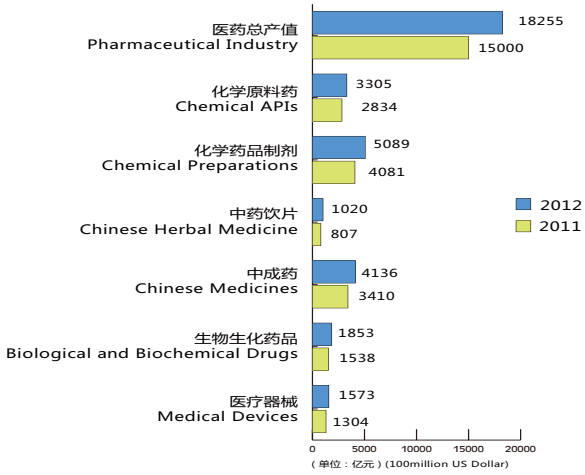
In addition, due to the national implementation of the newly revised pharmaceutical GMP, intensified energy saving and emission reduction, investment in pharmaceutical industry continued its rapid growth, whose annual total investment reached 356.5 billion yuan, with an annual growth of 34.6%, higher than the growth rate of total fixed asset investment by about 14 percentage points.

去年我国医药产值同比增长21.7%

日前，国家发改委发布统计数据显示，2012年，我国医药产业产值、对外贸易、经济效益、完成投资继续保持稳定增长，总体呈现平稳发展态势。

截至2012年底，我国医药产业总资产16408亿元，同比增长18.4%；完成产值18255亿元，同比增长21.7%。其中，化学原料药3305亿元，同比增长16.6%；化学药品制剂5089亿元，同比增长24.7%；中药饮片1020亿元，同比增长26.4%；中成药4136亿元，同比增长21.3%；生物生化药品1853亿元，同比增长20.5%；医疗器械1573亿元，同比增长20.6%。同期，医药产业工业增加值增长14.5%，高出工业平均增速4.5个百分点。

2012年我国医药产业产值情况
The output value of China's pharmaceutical in 2012



2012年，医药产业实现主营业务收入17950亿元，同比增长20.1%；利润总额1833亿元，同比增长20.4%，继续维持较高水平。其中，中药饮片、化学药品制剂增速较快，分别为27.5%和25.3%；化学原料药、中成药、生物生化药品增速稍低，分别为15.9%、16.9%和14.3%。同期，医药产业销售收入利润率约10.2%，同比基本持平。

同期，受欧美国家需求下降、部分国家进口标准提高等因素影响，医药产业进出

2012年我国医药产业利润同比增长情况
The profit of China's pharmaceutical in 2012

医药产业利润总额 Pharmaceutical Industry Profit	20.40%
化学药品制剂 Chemical Preparations	25.30%
化学原料药 Chemical APIs	15.90%
中药饮片 Chinese Herbal Medicine	27.50%
中成药 Chinese Medicines	16.90%
生物生化药品 Biological and Biochemical Drugs	14.30%

(March 12, 2013)

口贸易增速回落较大，全年累计进出口额810亿美元，同比增长10.5%。其中，出口额476亿美元，同比增长6.9%；进口额334亿美元，同比增长15.9%。

另外，由于国家实施新修订药品GMP、节能减排力度加大等原因，医药产业投资继续快速增长，全年累计完成投资3565亿元，同比增长34.6%，高出全社会固定资产投资增速约14个百分点。

（2013-03-12）

Notes: • All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.
• Read the electronic version of the newsletter please visit http://www.ccpie.org

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