2019. Volume 3

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

NMPA Launched China's Action Plan on Scientific Drug Administration

To comprehensively implement the *Four Strictest Requirements* for drug safety, as stated by General Secretary Xi Jinping, while focusing on the theme of *innovation, quality, efficiency, system, and ability*; to promote the innovation of the regulatory concept, system and mechanism; and to accelerate China's transition from a big country with numerous small pharmaceutical enterprises to a big country with strong pharmaceutical enterprises, on April 30, 2019, NMPA issued a Notice with decisions to carry out research on scientific administration over pharmaceuticals, medical devices and cosmetics, launch the China's Action Plan on Scientific Drug Administration, and identify the first nine key research projects.

The Notice pointed out that based on the actual situation of China's drug administration, while focusing on the reform and innovation of the drug review and approval system, and closely tracking the international regulatory frontiers, it is planned to develop a batch of supervision policies, technical specifications and guides for review, evaluation technologies for inspection and testing, technical standards within 3-5 years by innovating regulatory tools, standards and methods, to effectively solve the outstanding problems that affect and constrain drug innovation, quality, efficiency, and accelerate the modernization of drug governance systems and governance capabilities.

The first batch of Action Plan projects initiated covers nine researches on: 1. the technical evaluation and supervision system of cell and gene therapy products; 2. the safety evaluation and quality control of nano-drugs; 3. the Clinically oriented evaluation of TCM safety; 4. the post-marketing drug safety monitoring and evaluation methods; 5. technical evaluation of drug-device combination products; 6. the safety and effectiveness evaluation of AI-based medical devices; 7. Regulatory Science for new materials for medical devices; 8. methodologies of real-world data for clinical evaluation of medical devices; 9. methods for cosmetics safety evaluation.

(April 30, 2019)

NMPA Issued the *Announcement on Revising the Package Inserts of Bromocriptine Mesilate Tablets*

To further protect public medication safety, NMPA decided to revise the Entries of [Indications] and [Contraindications] of the package inserts of Bromocriptine Mesilate Tablets. On May 8, 2019, the relevant matters were announced as follows:

I. All manufacturers of Bromocriptine Mesilate Tablets shall, in accordance with the *Provisions for Drug Registration* and the requirements for the said revision, submit a supplementary application as such before June 29, 2019 to the state drug administration for record filing.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and insert sheets shall be consistent with those originally approved. All the insert sheets and labels of ex-factory drugs shall be changed within 6 months after the record filing of the supplementary application.

国家药品监督管理局启动中国药品监管科学行动计划

为全面贯彻落实习近平总书记有关药品安全“四个最严”要求，围绕“创新、质量、效率、体系、能力”主题，推动监管理念制度机制创新，加快推进我国从制药大国向制药强国迈进，2019年4月30日，国家药品监督管理局发布通知，决定开展药品、医疗器械、化妆品监管科学研究，启动实施中国药品监管科学行动计划，并确定首批九个重点研究项目。

通知指出，立足我国药品监管工作实际，围绕药品审评审批制度改革创新，密切跟踪国际监管发展前沿，拟通过监管工具、标准、方法等系列创新，经过3-5年的努力，制定一批监管政策、审评技术规范指南、检查检验评价技术、技术标准等，有效解决影响和制约药品创新、质量、效率的突出性问题，加快实现药品治理体系和治理能力现代化。

首批启动的行动计划项目共有九项，分别是细胞和基因治疗产品技术评价与监管体系研究、纳米类药物安全性评价及质量控制研究、以中医临床为导向的中药安全评价研究、上市后药品的安全性监测和评价方法研究、药械组合产品技术评价研究、人工智能医疗器械安全有效性评价研究、医疗器械新材料监管科学研究、真实世界数据用于医疗器械临床评价的方法学研究、化妆品安全性评价方法研究。

(2019-04-30)

国家药品监督管理局发布《关于修订甲磺酸溴隐亭片说明书的公告》

为进一步保障公众用药安全，国家药品监督管理局决定对甲磺酸溴隐亭片说明书【适应症】、【禁忌】等项进行修订。2019年5月8日，将有关事项公告如下：

一、所有甲磺酸溴隐亭片生产企业均应依据《药品注册管理办法》等有关规定，按照甲磺酸溴隐亭片说明书修订要求，提出修订说明书的补充申请，于2019年6月29日前报国家药品监管部门备案。

修订内容涉及药品标签的，应当一并进行修订；说明书及标签其他内容应当与原批准内容一致。在补充申请备案后6个月内对所有已出

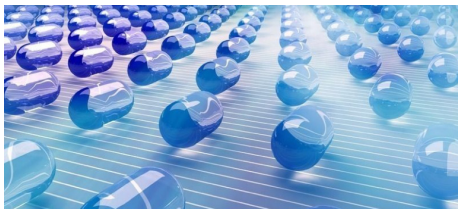
Published by
China Center for Food and Drug International Exchange
Servier (Tianjin) Pharmaceutical Co., Ltd.

The manufacturers of Bromocriptine Mesilate Tablets should conduct in-depth research on the occurrence mechanism of new adverse reactions, take effective measures to publicize the training on drug use and safety issues, and notify the drug distribution and end-user units in an appropriate and timely manner if the medication safety-related contents are changed, to guide the physician and pharmacist to use the medicine rationally.

II. The clinicians and pharmacists should carefully read the revised contents of the package inserts for Bromocriptine Mesilate Tablets. Drug options should be based on comprehensive benefit / risk analysis as per the new revisions.

III. The patients should carefully read the newly revised contents of the package inserts before use, and strictly comply with the medical orders.

(April 29, 2019)



厂的药品说明书及标签予以更换。

各甲磺酸溴隐亭片生产企业应当对新增不良反应发生机制开展深入研究，采取有效措施做好使用和安全性问题的宣传培训，涉及用药安全的内容变更要立即以适当方式通知药品经营和使用单位，指导医师、药师合理用药。

二、临床医师、药师应当仔细阅读甲磺酸溴隐亭片说明书的修订内容，在选择用药时，应当根据新修订说明书进行充分的效益／风险分析。

三、患者应严格遵医嘱用药，用药前应当仔细阅读说明书。

(2019-04-29)

NMPA issued the *Guidelines for the Construction of Drug Information Traceability System* and the *Encoding Requirement for Drug Traceability Codes*

To live up to the *Opinions of the General Office of the State Council on Accelerating the Construction of Traceability System for Important Products* (State Council General Office [2015] No. 95) and the *NMPA's Guiding Opinions on the Construction of Drug Information Traceability System* (NMPA [2018] No. 35) and other documents, and promote the construction of such system, NMPA organized the compilation of the two information standards of the *Guidelines for the Construction of Drug Information Traceability System and the Encoding Requirement for Drug Traceability Codes*, which have been released on April 26, 2019, and effective forthwith.

(April 28, 2019)

国家药品监督管理局发布《药品信息化追溯体系建设导则》《药品追溯码编码要求》

为贯彻落实《国务院办公厅关于加快推进重要产品追溯体系建设的意见》（国办发〔2015〕95号）和《国家药监局关于药品信息化追溯体系建设的指导意见》（国药监药管〔2018〕35号）等文件要求，推动药品信息化追溯体系建设，国家药监局组织编制了《药品信息化追溯体系建设导则》和《药品追溯码编码要求》两项信息化标准，于2019年4月26日发布，自发布之日起实施。

(2019-04-28)

NMPA Issued Announcement on Releasing *M4: Common Technical Document (CTD) for the Registration of Pharmaceuticals for Human Use (CTD)* Module 1 and its Chinese Translation

As per the relevant provisions of the former CFDA's *Announcement on Applying the ICH Secondary Guidelines* (No. 10 of 2018) (hereinafter referred to as Announcement No. 10 of 2018), NMPA organized the formulation of and released on April 17, 2019 the *Module 1: Administrative Information and Prescribing Information of M4: Common Technical Document for the Registration of Pharmaceuticals for Human Use* (hereinafter referred to as M4). As from July 1, 2019, the applicant shall submit dossiers in alignment with the Module 1. Requirements for registration application of drugs meeting conditions stipulated in the Announcement No. 10 of 2018.

Meanwhile, a Chinese version of the full text of the M4 Guidelines, the translation of which being organized by NMPA, was also released. (April 17, 2019)

国家药品监督管理局发布《M4：人用药物注册申请通用技术文档（CTD）》模块一文件及CTD中文版的通告

依据原食品药品监管总局《关于适用国际人用药品注册技术协调会二级指导原则的公告》（2018年第10号）（以下简称2018年第10号公告）有关规定，国家药品监督管理局组织制定了《M4：人用药物注册申请通用技术文档》（以下简称M4）模块一文件：行政文件和药品信息，于2019年4月17日发布。自2019年7月1日起，对2018年第10号公告规定情形的药品注册申请，申请人应按照M4模块一文件要求提交资料。

同时，国家药品监督管理局组织翻译了M4指导原则全文，形成了中文版，一并予以发布。(2019-04-17)

NMPA Released the Announcement on Standardizing the Requirements for Completing the *Customs Clearance Form for Imported Drugs* and other Application Forms for Import and Export Documents for Drugs

To further optimize the business environment at the port and promote cross-border trade facilitation, NMPA, in conjunction with the General Administration of Customs, is performing online verification of electronic data covering the *Customs Clearance Form for Imported Drugs*, the import and export permit for narcotic drugs, psychotropic substances, anabolic agents and peptide hormones drugs, etc. In order to ensure the accuracy and standard of data and improve the efficiency of electronic customs clearance, on April 2, 2019, NMPA released the Announcement on Standardizing the Requirements for Completing the *Customs Clearance Form for Imported Drugs* and other Application Forms for Import and Export Documents for Drugs, with the following specifications:

I. In the columns of the application form for receiving unit, unit applying for inspection, import unit, domestic export unit, the enterprise must fill in the 18-digit unified social credit code (no spaces) before the Chinese name of the unit, which should be consistent with the code contained in the business license and other certificates. No or incorrect code will affect the verification by the customs information system after the product is declared.

II The HS product code entered by the enterprise in the application form shall be a complete 10-digit number, and shall not be filled with any other characters or spaces, to avoid affecting the comparison and verification by the information system.

III. Where the enterprise fills in the port city or the border port of imported medicinal materials in the application form's columns of import port, port of entry, or domestic export port, etc., the entries shall be filled in accordance with the *Standard Name List of the Import Port City(Border Port)of Drugs(Medicinal Materials)(see annex)*). In the application form of the *Customs Clearance Form for Imported Drugs*, if the specific port is filled in, the name of the clearance zone (custom district) of the port must be filled in according to the Customs Clearance Code Table published on the website of the General Administration of Customs.

(April 2, 2019)

国家药品监督管理局发布关于规范《进口药品通关单》等药品进出口证件申请表填写要求的公告

为进一步优化口岸营商环境，促进跨境贸易便利化，国家药品监督管理局正在对《进口药品通关单》、麻醉药品和精神药物进（出）口准许证、蛋白同化制剂和肽类激素药品进（出）口准许证等证件同海关总署开展电子数据联网核查。为确保数据规范准确，提高电子通关效率，2019年4月2日，发布关于规范《进口药品通关单》等药品进出口证件申请表填写要求的公告，对企业填写上述证件申请表工作提出如下规范要求：

一、企业在申请表收货单位、报验单位、进口单位、境内出口单位等栏目中，须在该单位中文名称前填写其18位统一社会信用代码（不得加有空格），并同该单位营业执照等证照所载代码保持一致。无代码或代码有误将影响产品报关后海关信息系统的比对核查。

二、企业在申请表中所填HS商品编码须为完整的10位数字，不得填入其他任何字符或空格，以免影响信息系统的比对核查。

三、企业在申请表进口口岸、到岸港、境内出口口岸等栏目中如填写口岸城市或进口药材边境口岸，须按《药品（药材）进口口岸城市（边境口岸）规范名称表》（见附件）准确填写。在《进口药品通关单》申请表中如填写具体口岸，须按海关总署网站发布的海关关区代码表准确填写口岸的关区名称。

（2019-04-02）

General Administration of Customs and NMPA Issued the Announcement on Implementing Expanded Network Verification of Three Types of Regulatory Certificates Covering the *Customs Clearance Certificate for Imported Drugs*

On April 1, 2019, NMPA and the General Administration of Customs issued an Announcement on Implementing Expanded Network Verification of Three Types of Regulatory Certificates Covering the *Customs Clearance Certificate for Imported Drugs*, which reads as follows:

To further optimize the business environment at the port and promote cross-border trade facilitation, the General Administration of Customs and NMPA decided to fully implement, on the basis of the former pilot program, online electronic data verification on three types of regulatory documents such as the Customs Clearance Form for Imported Drugs. The relevant matters are hereby announced as follows:

海关总署 国家药品监督管理局发布关于《进口药品通关单》等3种监管证件扩大实施联网核查的公告

2019年4月1日，海关总署、国家药品监督管理局发布关于《进口药品通关单》等3种监管证件扩大实施联网核查的公告，内容如下：

为进一步优化口岸营商环境，促进跨境贸易便利化，海关总署、国家药品监督管理局决定在前期联网核查试点基础上，对《进口药品通关单》等3种监管证件全面实施电子数据联网核查。现将有关事项公告如下：

I. The promulgation of this Announcement marks the immediate nationwide implementation of network verification of the electronic data of *Customs Clearance Form for Imported Drugs*, *Drug Import Permit*, and *Drug Export Permit*, and electronic data of import and export goods declarations.

II. The drug administration department shall issue the above-mentioned documents as per the provisions of relevant laws and regulations, and transmit the electronic data of the documents to the customs, which shall conduct verification checks in the customs clearance and handle the import and export procedures as required. Regarding the documents issued before the implementation of network verification, the holders of such paper documents can handle the import and export procedures at the customs within the validity period.

III. Customs declaration enterprises may declare to the customs in a paperless manner as per the provisions of the paperless reform of customs clearance operations. On account of the audit requirements of the customs and drug administration departments, or failures of computer management systems and network communications, etc., it can be converted to paper declaration or supplemented with paper documents.

IV. Enterprises can log in to China International Trade *Single Window* to check the electronic data transmission status of the documents.

V. The China E-port Information Data Center is the technical support department for network verification. (April 1, 2019)

一、自本公告发布之日起，在全国范围内推广实施《进口药品通关单》《药品进口准许证》《药品出口准许证》电子数据与进出口货物报关单电子数据的联网核查。

二、药品监督管理部门根据相关法律法规的规定签发上述证件，将证件电子数据传输至海关，海关在通关环节进行比对核查，并按规定办理进出口手续。联网核查实施前已签发的证件，企业可凭纸质证件在有效期内向海关办理进出口手续。

三、报关企业按照海关通关作业无纸化改革的规定，可采用无纸方式向海关申报。因海关和药品监督管理部门审核需要，或计算机管理系统、网络通信故障等原因，可以转为有纸报关作业或补充提交纸质证件。

四、企业可登录中国国际贸易“单一窗口”查询证件电子数据传输状态。

五、中国电子口岸数据中心为联网核查的技术支持部门。

(2019-04-01)

Medical Devices

NMPA Issued Guidelines for Technical Review of the Registration and Clinical Evaluation of Centrifugal Blood Component Separation Equipment

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on May 15, 2019 the *Guidelines for Technical Review of the Registration and Clinical Evaluation of Centrifugal Blood Component Separation Equipment*.

(May 15, 2019)

医疗器械

国家药品监督管理局发布离心式血液成分分离设备临床评价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《离心式血液成分分离设备临床评价注册技术审查指导原则》，于2019年5月15日发布。 (2019-05-15)

NMPA Issued the *Guidelines for Technical Review of Service Life in the Registration of Active Medical Devices*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on May 14, 2019 the *Guidelines for Technical Review of Service Life in the Registration of Active Medical Devices*.

(May 14, 2019)

国家药品监督管理局发布有源医疗器械使用期限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《有源医疗器械使用期限注册技术审查指导原则》，于2019年5月14日发布。

(2019-05-14)

NMPA Issued Three Guidelines for Technical Review of the Registration of Dental Burs

To reinforce the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of and released on April 11, 2019 the *Guidelines for Technical Review of the Registration of Dental Burs, the Guidelines for Technical Review of the Registration of Disposable Dispensing Syringes, and the Guidelines for Technical Review of the Registration of Disposable Skin Stapler (2019 Revised Edition)*.

(April 11, 2019)

国家药品监督管理局发布牙科车针等3项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《牙科车针注册技术审查指导原则》《一次性使用配药用注射器注册技术审查指导原则》《一次性使用皮肤缝合器注册技术审查指导原则（2019年修订）》，于2019年4月11日发布。

（2019-04-11）

NMPA issued the *Announcement on Adjusting the Examination and Approval Process for Clinical Trials of Medical Devices*

On April 1, 2019, NMPA issued the Announcement on *Adjusting the Examination and Approval Process for Clinical Trials of Medical Devices*, which reads as follows:

As per 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), to further optimize the examination and approval procedures for clinical trials for medical devices, NMPA has adjusted the said procedures, and the relevant matters are hereby announced as follows:

Before submitting the application for clinical trial examination and approval, the applicant may, according to the *Announcement on the Relevant Matters Concerning the Communication of Medical Device Clinical Trial Applications for Approval* (CFDA Announcement No. 184 of 2017) and Center for Medical Device Evaluation. NMPA (hereinafter referred to as the CMDE). Within 60 working days from the date of acceptance and payment of the application for clinical trial examination and approval, the applicants can carry out clinical trials should they have not received the opinions of CMDE (including the notice of the expert consultation meeting and the notice for supplementary information) on the premise that their reserved contact information and the mailing address are valid. For the approval of the clinical trial, CMDE shall announce the acceptance number, the applicant's name and address, the name of the investigational medical device, its model specification, structure and composition on its website, and inform the applicant via the same website as well, while no longer issuing paper-based approval document.

Other requirements for the approval of medical device clinical trials shall be implemented in accordance with the *Provisions for Medical Device Registration* and other relevant regulations.

This Approval Process shall be implemented as of the date of promulgation.

(April 1, 2019)

国家药品监督管理局发布《关于调整医疗器械临床试验审批程序的公告》

2019年4月1日，国家药品监督管理局发布《关于调整医疗器械临床试验审批程序的公告》，内容如下：

为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），进一步优化临床试验审批程序，对医疗器械临床试验审批程序作出调整，现将有关事项公告如下：

申请人在提出临床试验审批申请前，可以根据《关于需审批的医疗器械临床试验申请沟通交流有关事项的通告》（国家食品药品监督管理总局通告2017年第184号）与国家药品监督管理局医疗器械技术审评中心（以下简称器审中心）进行沟通。自临床试验审批申请受理并缴费之日起60个工作日内，申请人在预留联系方式、邮寄地址有效的前提下，未收到器审中心意见（包括专家咨询会议通知和补充资料通知）的，可以开展临床试验。对于同意开展临床试验的，器审中心将受理号、申请人名称和住所、试验用医疗器械名称、型号规格、结构及组成在器审中心网站公布，并将审查结果通过器审中心网站告知申请人，不再发放临床试验批件。

其他关于医疗器械临床试验审批要求，按照《医疗器械注册管理办法》等相关规定执行。

本审批程序自发布之日起施行。

（2019-04-01）

Annual Report

NMPA Published the *2018 Annual Statistical Report on Drug Administration*

On May 9, 2019, NMPA issued the *2018 Annual Statistical Report on Drug Administration*, which is excerpted as follows:

I. Production and distribution licensing

(I) Drug production and distribution licensing

1. Drug production licensing

As of the end of November 2018, China has a total of 4,441 drug APIs and preparation manufacturers.

2. Drug distribution licensing

As of the end of November 2018, China has a total of 508,000 enterprises with *Drug Distribution Licenses*, including 14,000 wholesalers; 5,671 retail chain enterprises, 255,000 retail chain stores, and 234,000 retail pharmacies.

(II) Medical device production and distribution licensing

1. Medical device production licensing

As of the end of November 2018, China has a total of 17,000 medical device manufacturers, of which there are 7,513, 9,189, and 1,997 manufacturers that can produce Class I, Class II and Class III Devices, respectively.

2. Medical device distribution licensing

As of the end of November 2018, China has 511,000 distributors for Class II and Class III medical devices, of which 292,000 distribute only Class II medical device products, 67,000 distribute only Class III products, and 152,000 distribute Class II and Class III concurrently.

(III) Cosmetic production licensing

As of the end of November 2018, China has a total of 4,664 cosmetic manufacturers.

II. Registration approvals

(I) Drug registration

In 2018, CNDA approved a total of 312 applications for new drug clinical trials, along with 25 new drug production certificates plus approval numbers, 10 approval numbers; as well as 8 applications for clinical trials in accordance with NDA procedures.

In 2018, CNDA approved a total of 58 applications for clinical trials of generic drugs, and 464 applications for such productions.

In 2018, CNDA approved a total of 154 applications for clinical trials of imported drugs, and 90 applications for marketing of imported drugs.

In 2018, CNDA approved a total of 1,862 supplementary applications. Drug administration departments of all provinces (autonomous regions and municipalities) have approved a total of 3,276 drug supplementary applications, and 12,648 applications for record filing.

(II) Registration of medical devices

In 2018, China completed the record filing for a total of 22,167 Class I medical devices, and 1,885 imported (incl. from Hong Kong, Macao and Taiwan) Class I medical devices. China approved initial registration for a total of 4,402 domestic Class II medical devices, 668 domestic Class III medical devices, 358 imported (incl. from Hong Kong,

年报

国家药品监督管理局发布《2018年度药品监管统计年报》

2019年5月9日，国家药品监督管理局发布《2018年度药品监管统计年报》，摘要如下：

一、生产和经营许可情况

（一）药品生产和经营许可情况

1. 药品生产许可情况

截至2018年11月底，全国共有原料药和制剂生产企业4441家。

2. 药品经营许可情况

截至2018年11月底，全国共有《药品经营许可证》持证企业50.8万家，其中批发企业1.4万家；零售连锁企业5671家，零售连锁企业门店25.5万家；零售药店23.4万家。

（二）医疗器械生产和经营许可情况

1. 医疗器械生产许可情况

截至2018年11月底，全国实有医疗器械生产企业1.7万家，其中：可生产一类产品的企业7513家，可生产二类产品的企业9189家，可生产三类产品的企业1997家。

2. 医疗器械经营许可情况

截至2018年11月底，全国共有二、三类医疗器械经营企业51.1万家，其中，仅经营二类医疗器械产品的企业29.2万家，仅经营三类医疗器械产品的企业6.7万家，同时经营二、三类医疗器械产品的企业15.2万家。

（三）化妆品生产许可情况

截至2018年11月底，共有化妆品生产企业4664家。

二、注册审批情况

（一）药品注册情况

2018年在新药审批工作中国家局共批准新药临床312件，批准新药生产的新药证书及批准文号25件，批准文号10件；共批准按新药申请程序申报临床申请8件。

2018年共批准仿制药临床申请58件，生产申请464件。

2018年共批准进口药品临床申请154件，上市90件。

2018年国家局共批准药品补充申请1862件。全国各省（区、市）局共批准药品补充申请3276件，备案12648件。

（二）医疗器械注册情况

2018年，全国共完成境内第一类医疗器械备案22167件，进口第一类医疗器械（含港澳台）备案1885件；共批准境内第二类医疗器械首次注册4402件，境内第三类医疗器械首次注册668件，进口（含港澳台）第二

Macao and Taiwan) Class II medical devices, and 235 imported (incl. from Hong Kong, Macao and Taiwan) Class III medical devices. China approved registration renewals for 3,364 domestic Class II medical devices, 505 domestic Class III medical devices, 781 imported (incl. from Hong Kong, Macao and Taiwan) Class II medical devices, and 723 imported (incl. from Hong Kong, Macao and Taiwan) Class III medical devices. China approved alterations of registration for 3,037 domestic Class II medical devices, 526 domestic Class III medical devices, 860 imported (incl. from Hong Kong, Macao and Taiwan) Class II medical devices, and 862 imported (incl. from Hong Kong, Macao and Taiwan) Class III medical devices.

(III) Registration of cosmetics

In 2018, China has approved a total of 1,458 initial applications, 1,337 registration renewals, and 1,507 registration alterations for domestic special-purpose cosmetics; and approved 16,624 initial record filings, 3,281 registration renewals, and 1,661 registration alterations for imported non-special purpose cosmetics.

Note:

[1] The report data are sourced from the *Drug Administration Statistical Reporting System*, with data reporting period ranging from December 1, 2017 to November 30, 2018.

[2] For production licensing of medical devices: say, an enterprise producing both Class I and Class III products is counted separately as production enterprise of Class I and Class III devices, and as 1 in total number of enterprises.

[3] For distribution licensing of medical devices: say, an enterprise operating both Class II and Class III devices is included in the respective categories while counting.

(May 9, 2019)

类医疗器械首次注册358件，进口（含港澳台）第三类医疗器械首次注册235件。批准境内第二类医疗器械延续注册3364件，境内第三类医疗器械延续注册505件，进口（含港澳台）第二类医疗器械延续注册781件，进口（含港澳台）第三类医疗器械延续注册723件。批准境内第二类医疗器械许可事项变更3037件，境内第三类医疗器械许可事项变更526件，进口（含港澳台）第二类医疗器械许可事项变更860件，进口（含港澳台）第三类医疗器械许可事项变更862件。

（三）化妆品注册情况

2018年共批准国产特殊用途化妆品首次申报1458件，延续1337件，变更1507件；批准进口非特殊用途化妆品首次备案16624件，延续3281件，变更1661件。

注：

[1] 本报告数据来源于《药品监督管理统计报表制度》。数据报告期为2017年12月1日至2018年11月30日。

[2] 医疗器械生产许可情况：例如，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1家。

[3] 医疗器械经营许可情况：例如，同时经营二类和三类的企业在统计时分别计入各自类别。

（2019-05-09）

Special Focus　业界专题

China's TCM imports and exports grew hand in hand in 2018

In 2018, China's trade in traditional Chinese medicine products achieved substantial growth, with good development momentum. According to customs statistics, the total export-import volume of TCM trade in China reached 5.768 billion U.S. dollars in 2018, up by 10.99% YOY. Among them, the export value was 3.909 billion US dollars, up by 7.39% YOY; the import value was 1.859 billion US dollars, up by 19.38%.

2018年我国中药类商品进出口双增长

2018年，我国中药类商品贸易实现大幅增长，发展势头良好。海关统计数据显示，2018年我国中药贸易进出口总额达57.68亿美元，同比增长10.99%。其中，出口额为39.09亿美元，同比增长7.39%；进口额为18.59亿美元，同比增长19.38%。

图1. 2018年我国中药类商品出口趋势
Figure 1. Tendency chart of China's TCM exports in 2018

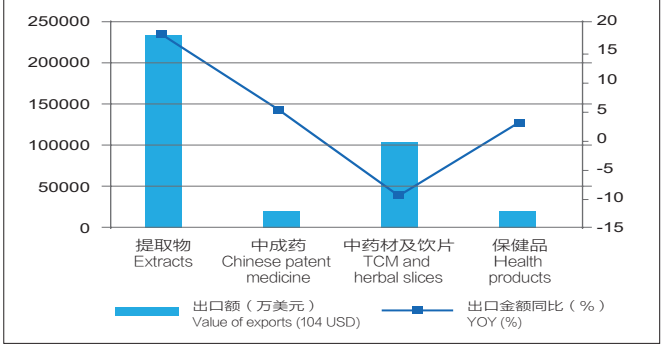
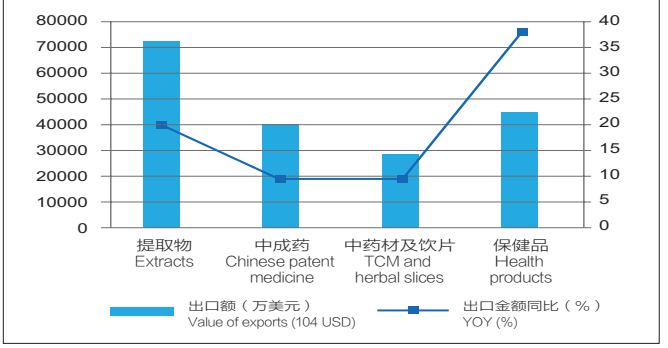


图2. 2018年我国中药类商品进口趋势
Figure 2. Tendency chart of China's TCM imports in 2018



(Excerpt from: China Pharmaceutical News, May 15, 2019)　（摘自：中国医药报2019-05-15）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.

• For electronic version of the Newsletter please visit http://www.ccfdie.org

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。

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