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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

The State Council Executive Meeting Passed the *Regulation for Supervision of Cosmetics (Draft)*

On January 3, 2020, Premier Li Keqiang presided over an executive meeting of the State Council. In the meeting, the *Regulation for Supervision of Cosmetics (Draft)* was approved. According to the requirements of attaching equal importance to power delegation and strong regulation, the Draft, as adopted by the Meeting, requires to implement risk-specific registration and filing management of cosmetic products and raw materials, and simplify the process; to improve regulatory measures, clarify the enterprises' principal responsibility for quality and safety of cosmetics, beef up punishment for violations of the law, substantially increase the amount of fines, add penalty provisions covering fines and industry debarment for those responsible, to promote the development of cosmetics and Beauty Care with guaranteed quality and safety well received by consumers.

(January 6, 2020)

国务院常务会议通过《化妆品监督管理条例（草案）》

2020年1月3日，国务院总理李克强主持召开国务院常务会议，会议通过了《化妆品监督管理条例（草案）》。按照放管并重要求，规定对化妆品产品和原料按风险高低分别实行注册和备案管理，并简化流程；完善监管措施，明确企业对化妆品质量安全的主体责任，加大违法惩戒力度，大幅提高罚款数额，增加对相关责任人的罚款、行业禁入等罚则，促进发展质量安全有保障、广大消费者喜爱的化妆品和“美丽产业”。

（2020-01-06）

NMPA Issued the *Announcement on the Guidelines for Real-World Evidence to Support Drug Development and Review (Interim)*

To further guide and standardize the use of real-world evidence in drug R&D and review, and ensure the quality and efficiency of drug R&D, NMPA has organized the formulation of the *Guidelines for Real-World Evidence to Support Drug Development and Review (Interim),* which has been released on January 7, 2020.

(January 7, 2020)

《关于真实世界证据支持药物研发与审评的指导原则（试行）》发布

为进一步指导和规范真实世界证据用于支持药物研发和审评的有关工作，保障药物研发工作质量和效率，国家药品监督管理局组织制定了《真实世界证据支持药物研发与审评的指导原则（试行）》，于2020年1月7日 发布。

（2020-01-07）

NMPA Issued the *Administrative Measures for Key Laboratories of NMPA*

To standardize the application and review, operation and management, assessment and evaluation of key laboratories of NMPA, and to improve the capacity and level of drug regulatory technology development, NMPA has organized the formulation of and released on January 6, 2020 the *Administrative Measures for Key Laboratories of NMPA*. Medical products administrations of all provinces, autonomous regions, and municipalities directly under the Central Government, the Xinjiang Production and Construction Corps, and all relevant units shall strictly implement these Measures.

(January 6, 2020)

国家药品监督管理局印发《国家药品监督管理局重点实验室管理办法》

为规范国家药品监督管理局重点实验室的申请与评审、运行与管理、考核与评估等管理工作，提升药品监管科技发展能力和水平，国家药品监督管理局组织制定了《国家药品监督管理局重点实验室管理办法》，于2020年1月6日 发布，请各省、自治区、直辖市药品监督管理局，新疆生产建设兵团药品监督管理局，各有关单位遵照执行。

（2020-01-06）

Published by
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Servier (Tianjin) Pharmaceutical Co., Ltd.

NMPA Issued the *Guidelines for Adverse Event Classification Standards for Clinical Trials of Preventive Vaccines*

To further standardize the safety evaluation of clinical trials of preventive vaccines and accelerate the integration of adverse event classification standards with international standards, NMPA has organized the drafting of and released on December 31, 2019 the *Guidelines for Adverse Event Classification Standards for Clinical Trials of Preventive Vaccines*. The *Guidelines for Adverse Reaction Classification Standards for Clinical Trials of Preventive Vaccines*, issued by the former State Food and Drug Administration (SFDA Department of Drug Registration [2005] No. 493) in 2005, shall be repealed simultaneously.

(December 31, 2019)

国家药品监督管理局发布《预防用疫苗临床试验不良事件分级标准指导原则》

为进一步规范预防用疫苗临床试验的安全性评价，加快不良事件分级标准与国际接轨，国家药品监督管理局组织起草了《预防用疫苗临床试验不良事件分级标准指导原则》，于2019年12月31日 发布。2005年原国家食品药品监督管理局发布的《预防用疫苗临床试验不良反应分级标准指导原则》（国食药监注〔2005〕493号）废止。 (2019-12-31)

NMPA issued the *Announcement on Enabling the Pharmaceutical Business Application System*

To implement the work requirements of the Executive Meeting of the State Council on online application and processing of import and export supervision documents, NMPA has integrated the development of a drug business application system to this end, covering the certificates for drug export sales, APIs exporting to EU drug substance, import and export of narcotic drugs and psychotropic substances, and the initial import of medicinal materials, etc.

The system was launched on December 31, 2019, also with the functions of online application and processing of the R&D project approval of narcotic drugs and psychotropic drugs, and the record filing of TCM extracts. For detailed operating instructions, please see the attachment (Omitted). Where the drug export sales certificate and the certification documents for EU-bound export of APIs are filed in the self-built system of the provincial drug regulatory department in the locality, the self-built system may still apply.

(December 31, 2019)

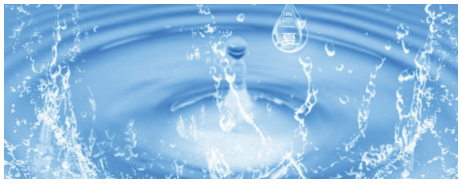
国家药品监督管理局发布《关于启用药品业务应用系统的公告》

为落实国务院常务会议关于进出口环节监管证件实现网上申报、网上办理的工作要求，国家药品监督管理局整合开发了药品业务应用系统，用于进出口环节药品监管证件业务办理，包括药品出口销售证明、出口欧盟原料药证明文件、麻醉药品和精神药品进出口准许证、首次进口药材等事项。该系统同时具备麻醉药品和精神药品研制立项、中药提取物备案的网上申请与办理功能。

该系统于2019年12月31日启用，操作说明详见附件（略）。如药品出口销售证明、出口欧盟原料药证明文件申请是在所在地省级药品监督管理部门自建系统填报的，可继续按原方式办理。 (2019-12-31)

NMPA Issued the *Notice on Enabling the Import and Export Permit Management System*

To implement the requirements set forth in the *State Council's Notice on the Issuance of Work Plan for Optimizing the Business Environment at Ports to Promote Cross-Border Trade Facilitation* (State Council [2018] Notice No. 37) and the State Council's requirements for online application and online processing of all import and export supervision documents before the end of 2019, NMPA and the General Administration of Customs jointly established a drug import and export permit management system on the One-stop Window Public Platform for International Trade. On December 27, 2019, NMPA issued the *Notice on Enabling the Import*



国家药品监督管理局发布《关于启用药品进出口准许证管理系统的通知》

为落实《国务院关于印发优化口岸营商环境促进跨境贸易便利化工作方案的通知》（国发〔2018〕37号）和国务院关于2019年底前进出口环节监管证件全部实现网上申报、网上办理的要求，国家药品监督管理局与海关总署国家口岸管理办公室共同在国际贸易“单一窗口”公共平台上建设了药品进出口准许证管理系统，2019年12月27日，国家药品监督管理局发布《关于启用药品进出口准许证管理系统的通知》。通知明确，药

and Export Permit Management System, which clearly states that the drug import and export permit management system has been officially launched since December 25, 2019, and shall be used to handle online the whole-process application, acceptance, approval and network verification of import and export of anabolic agents and peptide hormones.

(December 27, 2019)

品进出口准许证管理系统自2019年12月25日起正式启用，用于在网上全程办理蛋白同化制剂和肽类激素进出口的申请、受理、审批和联网核查等业务。 (2019-12-27)

NMPA Issued the *Technical Guidelines for Clinical Comparability Exercise of Preventive Vaccines*

To further standardize and improve the clinical R&D of vaccines and strengthen the supervision of vaccine quality and safety, NMPA has organized the formulation of the *Technical Guidelines for Clinical Comparability Exercise of Preventive Vaccines*, which has been released on December 24, 2019.

(December 24, 2019)

国家药品监督管理局发布《预防用疫苗临床可比性研究技术指导原则》

为进一步规范和提高疫苗临床研发水平，加强疫苗质量安全监管，国家药品监督管理局组织制定了《预防用疫苗临床可比性研究技术指导原则》，于2019年12月24日 发布。 (2019-12-24)

NMPA Issued the *Guidelines for Clinical Trials of Drugs for Treatment of Nonalcoholic Steatohepatitis (Interim)*

To guide and standardize the clinical trials of drugs for non-alcoholic steatohepatitis, NMPA has organized the formulation of the *Guidelines for Clinical Trials of Drugs for Treatment of Nonalcoholic Steatohepatitis (Interim)*, which was released on December 20, 2019.

(December 20, 2019)

国家药品监督管理局发布《非酒精性脂肪性肝炎治疗药物临床试验指导原则（试行）》

为指导和规范非酒精性脂肪性肝炎治疗药物临床试验，国家药品监督管理局组织制定了《非酒精性脂肪性肝炎治疗药物临床试验指导原则（试行）》，于2019年12月20日发布。 (2019-12-20)

NMPA Issued the *Announcement on Enabling the New Version of Management System for Import Filing of Drugs and Medicinal Materials*

To implement the Regulations on Optimizing the Business Environment in China, NMPA and the General Administration of Customs have collaboratively established a management system for import filing of pharmaceuticals and medicinal material imports (hereinafter referred to as the filing system), relying on the *One-stop Window* Public Platform for International Trade. On December 19, 2019, the *Announcement on Enabling the New Version of Management System for Import Filing of Drugs and Medicinal Materials* was issued to officially launch the filing system on the date of issuance, and the applicants for Inspection shall log in at http://www.singlewindow.cn to submit Drug import filing application.

(December 19, 2019)

国家药品监督管理局发布《关于启用新版药品和药材进口备案管理系统的公告》

为贯彻落实《优化营商环境条例》，国家药品监督管理局与海关总署依托国际贸易“单一窗口”，合作建设了药品和药材进口备案管理系统（以下称备案系统）。2019年12月19日，发布《关于启用新版药品和药材进口备案管理系统的公告》，备案系统自2019年12月25日起正式启用，报验单位登录http://www.singlewindow.cn 提交药品进口备案申请。 (2019-12-19)

NMPA Issued the *Technical Guidelines for Aluminum-Adjuvant-containing Preventive Vaccines*

To standardize and guide the R&D of aluminum-adjuvant-containing vaccines, and to strengthen the production and quality control thereof, NMPA has organized the formulation of the *Technical Guidelines for Aluminum-Adjuvant-containing Preventive Vaccines,* which has been released on December 10, 2019.

(December 10, 2019)

国家药品监督管理局发布《预防用含铝佐剂疫苗技术指导原则》

为规范和指导含铝佐剂疫苗的研发，加强铝佐剂及含铝佐剂疫苗的生产和质量控制，国家药品监督管理局组织制定了《预防用含铝佐剂疫苗技术指导原则》，于2019年12月10日发布。（2019-12-10）

NMPA Issued the *Announcement on Issues Pertaining to the Implementation of the Drug Administration Law of the People's Republic of China*

On November 29, 2019, NMPA issued the Announcement on Issues Pertaining to the Implementation of the *Drug Administration Law of the People's Republic of China* (2019 No. 103), which reads as follows:

Revised and adopted by the Twelfth Session of the Standing Committee of the 13th National People's Congress on August 26, 2019, the revised Drug Administration Law of the People's Republic of China (hereinafter referred to as DAL) shall be implemented as from December 1, 2019. NMPA is stepping up work on the development, formulation and revision of supporting regulations, normative documents and technical guidelines, which will be released in accordance with procedures. We hereby announce the issues pertaining to the implementation of the newly revised DAL as follows:

I. The Drug Marketing Authorization Holder System

The newly revised DAL takes the drug marketing authorization holder (MAH) system into full swing. Starting from December 1, 2019, all undertakings or drug R&D institutions holding drug registration certificates (drug approval numbers, import drug registration certificates, or medical product registration certificates) shall be taken as drug MAHs, who should strictly perform their corresponding obligations, and take responsibility for drug safety, effectiveness and quality controllability in the whole process of drug R&D, production, distribution and use.

II. Record-filing management of clinical trial institutions

As from December 1, 2019, drug clinical trial institutions (DCTIs) shall be, invariably, subject to record filing management. DCTI-qualification applications accepted before December 1, 2019, with pending examination & approval results, shall be subject to record filing per the current regulations.

III. Requirements for drug GMP and GSP administration

As from December 1, 2019, drug GMP and GSP certifications shall be cancelled, and the corresponding applications / certificates shall be no longer accepted / issued. Certification applications accepted before December 1, 2019 shall be processed in accordance with the relevant provisions of the original drug GMP and GSP certification. To applications with on-site inspection completed and conformance to requirements before December 1, 2019, drug GMP and GSP

国家药品监督管理局印发关于贯彻实施《中华人民共和国药品管理法》有关事项的公告

2019年11月29日，国家药品监督管理局印发关于贯彻实施《中华人民共和国药品管理法》有关事项的公告（2019年第103号），内容如下：

《中华人民共和国药品管理法》（以下称药品管理法）已由第十三届全国人大常委会第十二次会议于2019年8月26日修订通过，自2019年12月1日起施行。国家药品监督管理局正在抓紧开展配套规章、规范性文件和技术指南的制修订工作，并将按程序陆续发布。现就贯彻实施新修订的药品管理法有关事项公告如下：

一、关于药品上市许可持有人制度

新修订的药品管理法全面实施药品上市许可持有人制度。自2019年12月1日起，凡持有药品注册证书（药品批准文号、进口药品注册证、医药产品注册证）的企业或者药品研制机构为药品上市许可持有人，应当严格履行药品上市许可持有人义务，依法对药品研制、生产、经营、使用全过程中药品的安全性、有效性和质量可控性负责。

二、关于临床试验机构备案管理

自2019年12月1日起，药物临床试验机构实施备案管理。2019年12月1日以前已经受理尚未完成审批的临床试验机构资格认定申请，不再继续审批，按照规定进行备案。

三、关于药品GMP、GSP管理要求

自2019年12月1日起，取消药品GMP、GSP认证，不再受理GMP、GSP认证申请，不再发放药品GMP、GSP证书。2019年12月1日以前受理的认证申请，按照原药品GMP、GSP认证有关规定办理。2019年12月1日前完成现场检查并符合要求的，发放药品GMP、GSP证书。凡现行法规要求进行现

certificates can be issued. On-site inspection shall be carried out even after December 1, 2019, where the current regulations require it, and the corresponding results shall be notified to the enterprise; non-compliance found in the inspections shall be dealt with in accordance with regulations pursuant to the Law.

IV. Associated review & approval for chemical APIs

Starting from December 1, 2019, no drug registration certificate will be issued for chemical APIs, whose manufacturers shall register on the AEP (APIs, pharmaceutical excipients, packaging materials and containers in direct contact with pharmaceuticals) registration platform for associated review & approval.

V. Investigation and prosecution of drug-related illegal activities

For illegal activities occurred before December 1, 2019 in drug R&D, production, distribution, and use, the former DAL (unrevised) shall apply, barring those deemed by the newly revised DAL as overestimated or underestimated activities, for which the newly revised DAL shall prevail. For illegal activities occurred after December 1, the newly revised DAL shall apply.

Drug regulatory authorities at all levels must resolutely implement the *Four Strictest (Strictest Standards, Regulation, Punishment, and Accountability)* Requirements for drug safety, strengthen the publicity and implementation of the newly revised DAL, further strengthen supervision and inspection, urge enterprises to continue to comply with production & distribution protocols, and strictly investigate and punish all kinds of illegal acts, to effectively safeguard medication safety for the general public. (November 29, 2019)

场检查的，2019年12月1日后应当继续开展现场检查，并将现场检查结果通知企业；检查不符合要求的，按照规定依法予以处理。

四、关于化学原料药一并审评审批

2019年12月1日起，对化学原料药不再发放药品注册证书，由化学原料药生产企业在原辅包登记平台上登记，实行一并审评审批。

五、关于药品违法行为查处

药品研制、生产、经营、使用违法行为发生在2019年12月1日以前的，适用修订前的药品管理法，但新修订的药品管理法不认为违法或者处罚较轻的，适用新修订的药品管理法。违法行为发生在12月1日以后的，适用新修订的药品管理法。

各级药品监管部门要坚决贯彻药品安全“四个最严”要求，加强新修订的药品管理法的宣传贯彻工作，进一步加大监督检查力度，督促企业生产经营行为持续合规，依法严厉查处各类违法违规行为，切实维护广大人民群众用药安全。 (2019-11-29)

NMPA and NHC Jointly Issued the *Announcement on Regulations for the Administration of Drug Clinical Trial Institutions*

According to the newly revised *Drug Administration Law of the People's Republic of China*, drug clinical trial institutions shall be subject to record filing management in lieu of accreditation. NMPA has formulated, in conjunction with the National Health and Health Commission (NHC), the *Regulations for the Administration of Drug Clinical Trial Institutions*, which has been released on November 29, 2019, and shall take effect as from December 1, 2019.

(November 29, 2019)

国家药品监督管理局 国家卫生健康委发布《关于药物临床试验机构管理规定的公告》

根据新修订《中华人民共和国药品管理法》的规定，药物临床试验机构由资质认定改为备案管理。国家药品监督管理局会同国家卫生健康委员会制定《药物临床试验机构管理规定》，于2019年11月29日发布，自2019年12月1日起施行。 (2019-11-29)

NMPA Issued the *Announcement on Cancellation of 68 Certification Items (Third Batch)*

As per the *Notice of the General Office of the State Council on Effective Clearance of Certification Items* (State Council General Office [2018] No. 47), to further reduce redundant certification for the convenience of the people and service optimization, NMPA decided to cancel 68 certification items (attachment, omitted) and issued an Announcement on November 29, 2019. Of the 68 listed items, Items 1 to 45 shall cease to be implemented from the date of this announcement, and Item 46 to 68 of the Annex shall cease to be implemented from December 1, 2019.

(November 29, 2019)

国家药品监督管理局发布关于取消68项证明事项的公告（第三批）

根据《国务院办公厅关于做好证明事项清理工作的通知》（国办发〔2018〕47号）要求，为进一步减证便民、优化服务，国家药品监督管理局决定取消68项证明事项（通知略），于2019年11月29日发布。通知所列第1项至第45项证明事项自本公告发布之日起停止执行，通知所列第46项至第68项证明事项自12月1日起停止执行。 (2019-11-29)

NMPA Issued the *Notice on the Implementation Plan of the State Council for Full-Coverage Pilot Reform of Separated Management of Permit and License in the Free Trade Pilot Areas*

As per the *Notice of the State Council on the Implementation of the Full-Coverage Pilot Reform of Separated Management of Permit and License* in Free Trade Pilot Areas (State Council [2019] No. 25, hereinafter referred to as Document 25), to comprehensively and solidly promote this Reform in the field of drug supervision, on November 29, 2019, NMPA issued a corresponding pilot implementation plan covering five parts: the guiding ideology, the scope and content of the pilot, the classified promotion of the reform of the examination and approval system, the improvement of the supporting measures for reform, and the effective implementation of the reform policy; and requiring conscientious implementation by drug administration departments and relevant units in Shanghai, Guangdong, Tianjin, Fujian, Liaoning, Zhejiang and other free trade pilot zones.

(November 27, 2019)

《国家药品监督管理局贯彻落实国务院在自由贸易试验区开展“证照分离”改革全覆盖试点实施方案》印发

为贯彻落实《国务院关于在自由贸易试验区开展“证照分离”改革全覆盖试点的通知》（国发〔2019〕25号，以下简称25号文件）要求，全面扎实推进药品监管领域“证照分离”改革各项工作，2019年11月29日，国家药品监督管理局印发关于贯彻落实国务院在自由贸易试验区开展“证照分离”改革全覆盖试点实施方案，方案包括指导思想、试点范围和内容、分类推进审批制度改革、完善改革配套措施和切实抓好改革政策落实五个部分，要求上海、广东、天津、福建、辽宁、浙江等自由贸易试验区药品监督管理局及有关单位认真贯彻落实。（2019-11-27）

Medical Devices

NMPA Issued the *Guidelines for Nomenclature for Common Names of Medical Devices*

To further standardize the common names of medical devices and guide the compilation of nomenclature guidelines for various professional fields of medical devices, NMPA has organized the formulation of the *Guidelines for Nomenclature for Common Names of Medical Devices*, which has been issued on December 25, 2019.

(December 25, 2019)

医疗器械

国家药品监督管理局发布《医疗器械通用名称命名指导原则》

为进一步规范医疗器械通用名称，指导医疗器械各专业领域命名指导原则的编制，国家药品监督管理局组织制定了《医疗器械通用名称命名指导原则》，于2019年12月25日发布。（2019-12-25）

NMPA Issued the *Guidelines for Conditional Approval for Marketing of Medical Devices*

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 Review & Approval System to Encourage Innovation in Drugs and Medical Devices*, to address the need for clinical treatment of severely life-threatening diseases, and speed up the review & approval of related medical devices, NMPA organized the formulation of and released on December 20, 2019 the *Guidelines for Conditional Approval for Marketing of Medical Devices*.

(December 20, 2019)

国家药品监督管理局发布《医疗器械附条件批准上市指导原则》

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》，解决严重危及生命疾病的临床治疗需求，加快相关医疗器械的审评审批，国家药品监督管理局组织制定了《医疗器械附条件批准上市指导原则》，于2019年12月20日发布。（2019-12-20）

NMPA Announces New and Revised Catalogues of Medical Devices Exempted from Clinical Trials

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*, and the State Council's requirements for deepening the reform of *Streamlining Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation and Optimizing Services*, to further improve the management of medical device registration, according to the *Regulations for the Supervision and Administration of Medical Devices, Provisions for Medical Device Registration*, and *Provisions for Registration of In Vitro Diagnostic Reagents,* NMPA organized the formulation of new and revised catalogs (omitted) of medical devices and in vitro diagnostic reagents exempt from clinical trials, which have been announced on December 20, 2019, and will take effect from the date of promulgation.

(December 20, 2019)

国家药品监督管理局公布新增和修订的免于进行临床试验医疗器械目录

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》、国务院深化“放管服”改革要求，进一步做好医疗器械注册管理工作，根据《医疗器械监督管理条例》《医疗器械注册管理办法》《体外诊断试剂注册管理办法》，国家药品监督管理局组织制定了新增和修订的免于进行临床试验医疗器械目录、新增和修订的免于进行临床试验体外诊断试剂目录（略）。于2019年12月20日公布，自公布之日起施行。 (2019-12-20)

Medical Device Unique Identification Database Goes Online

Medical device unique identification database constitutes an important part of the medical device unique identification system. In accordance with the requirements of the *Rules for Unique Identification System for Medical Devices and the deployment of the Pilot Work Plan for Medical Device Unique Identification System*, the medical device unique identification database was officially launched on December 10, 2019, with functions opened to pilot enterprises to apply for related data of unique identification of pilot varieties.

In the next step, NMPA will strengthen guidance and services for the application of unique identification data for medical devices, and open the unique identification database query and sharing services to the pilot units in March 2020 in accordance with the pilot work deployments.

(December 10, 2019)

医疗器械唯一标识数据库上线

医疗器械唯一标识数据库是医疗器械唯一标识系统的重要组成部分。按照《医疗器械唯一标识系统规则》的要求和《医疗器械唯一标识系统试点工作方案》的安排，医疗器械唯一标识数据库于2019年12月10日正式上线，面向试点企业开放针对试点品种的唯一标识相关数据申报功能。

下一步，国家药品监督管理局将加强对医疗器械唯一标识数据申报的指导与服务，按照试点工作安排，于2020年3月向试点单位开放唯一标识数据库查询与共享服务。

(2019-12-10)

News Information

The State Council's Leading Group for Deepening the Reform of the Medical and Health System Issued the *Notice on Policies and Measures to Further Deepen the Reform of the Medical and Health System with Centralized Procurement & Use of Drugs as a Breakthrough*

On November 29, 2019, approved by the State Council, the Leading Group for Deepening the Reform of the Medical and Health System Issued the *Notice on Several Policies and Measures to Further Deepen the Reform of the Medical and Health System with Centralized Procurement & Use of Drugs as a Breakthrough* in order to implement the decisions and plans of the CPC central Committee and the State Council on deepening the reform of the medical and health care systems and promote the interlocked reform of health care, health insurance, and pharmaceuticals.

综合报道

国务院深化医药卫生体制改革领导小组印发《关于以药品集中采购和使用为突破口进一步深化医药卫生体制改革若干政策措施的通知》

为贯彻落实党中央、国务院关于深化医药卫生体制改革的决策部署，推动各地加大力度持续深化医疗、医保、医药联动改革，经国务院同意，国务院深化医药卫生体制改革领导小组于2019年11月29日印发《关于以药品集中采购和使用为突破口进一步深化医药卫生体制改革若干政策措施的通知》。

通知指出，要推进实施以下政策措施，促进医疗、医保、医药联动，放大改革效

The Notice pointed out that it is necessary to promote the interlocked reform of health care, health insurance, and pharmaceuticals, magnify the effects of reform, and better address the problems complicating medical services to the people, the following policies and measures shall be implemented, covering 15 aspects:

1. Deepening the reform of state-led centralized procurement and use of drugs
2. Establishing a national pharmaceutical public procurement market and a multi-party interlocked procurement structure
3. Improving the quality of drugs
4. Ensuring stable supply of drugs
5. Hoisting the efficiency of drug payment
6. Promoting the construction of a unified and open pharmaceutical production & distribution market nationwide
7. Promoting interlocked reforms such as the dynamic adjustment of medical service prices
8. Vigorously promoting the reform of the salary system for health staff
9. Strengthening the standardized management of medical institutions' prescription practices
10. Promoting the implementation of medical insurance payment standards for drugs
11. Deepening the reform of medical insurance payment methods
12. Ameliorating the supervision mechanism of medical insurance funds
13. Promoting fine-grained supervision of medical services
14. Improving the national drug price monitoring system
15. Accelerating the application of IT in healthcare (December 2, 2019)

应，更好推动解决群众看病就医问题。通知共有12个方面的内容。

一、全面深化国家组织药品集中采购和使用改革

二、构建全国药品公共采购市场和多方联动的采购格局

三、提升药品质量水平

四、确保药品稳定供应

五、提升药品货款支付效率

六、推动构建全国统一开放的药品生产流通市场格局

七、推进医疗服务价格动态调整等联动改革

八、大力推进薪酬制度改革

九、加强医疗机构用药规范管理

十、推动实施药品医保支付标准

十一、深化医保支付方式改革

十二、完善医保基金监管机制

十三、推进医疗服务精细化监管

十四、健全全国药品价格监测体系

十五、加快推进信息化建设

(2019-12-02)

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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