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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

NMPA Minister Jiao Hong Attended A Special Press Briefing on the *Vaccine Administration Law* Held by the General Office of the NPC Standing Committee and Purported to Impose the Strictest Administration Over Vaccines

In the afternoon of June 29, the General Office of the NPC Standing Committee held a special press briefing on the *Vaccine Administration Law of the People's Republic of China*, passed by voting the same day at the Eleventh Session of the Standing Committee of the Thirteenth National People's Congress (NPC). NMPA Minister Jiao Hong attended the briefing and answered questions from reporters by stating that the V*accine Administration Law* (hereinafter referred to as the Law) shall fully implements General Secretary Xi Jinping's *Four Strictest (Standards, Regulation, Punishment, and Accountability)* requirements for drugs, to impose whole-process, all-aspect and multi-faceted strict supervision over vaccines to ensure their safety, effectiveness, accessibility and quality enhancement, and beef up people's confidence in vaccine safety in China.

Jiao expressed that vaccine, as a special medicine, is a national strategic product featuring public welfare. In response to the characteristics of vaccines, the *Law* clearly states that the State implements the most stringent management system for vaccines, and proposes special systems and regulations for the whole process of vaccine development, production, circulation and vaccination. Furthermore, the *Law* has meted out penalties far heavier than those for the general drugs for the production and sale of counterfeit and substandard vaccines and other illegal acts, stressing that the penalties shall be specific and severe to offenders in terms of their qualification, property, and personal freedom.

Jiao emphasized that the *Law* also takes into account safety, development and innovation. To actively promote the further improvement of the quality of vaccines in China, the Law has made a series of new regulations to encourage the innovation and development of vaccines.

Jiao pointed out that since the founding of the People's Republic of China, especially since the reform and opening up, China's vaccine industry has achieved rapid development. China has become one of the few countries in the world that can be self-reliant for all planned immunization vaccines. China's National Regulatory Authority for Vaccines passed WHO assessment in 2010 and reassessment in 2014, and is currently poised for a new round of WHO assessment. Taking the enactment of the *Law* as an opportunity, we are to comprehensively improve China's drug and vaccine regulatory system, consolidate supervision capabilities, better serve the development of the vaccine industry, protect the drug safety for the people, and promote the transition from quantity-extensive to quality-intensive vaccine administration.

(June 30, 2019)

全国人大常委会办公厅举办《疫苗管理法》专题新闻发布会，焦红出席并指出——对疫苗实施最严格管理制度

6月29日，《中华人民共和国疫苗管理法》经十三届全国人大常委会第十一次会议表决通过。当天下午，全国人大常委会办公厅以《疫苗管理法》为专题举办新闻发布会。国家药监局局长焦红出席发布会并回答记者提问。焦红指出，《疫苗管理法》全面贯彻落实习近平总书记关于药品“四个最严”的要求，将对疫苗实施全过程、全环节、全方位的严格监管，以保障疫苗安全、有效、可及，进一步促进我国疫苗质量的提升，增强人民群众对疫苗安全的信心。

焦红表示，疫苗是特殊的药品，是国家战略性、公益性产品。针对疫苗特点，《疫苗管理法》明确提出国家对疫苗实行最严格的管理制度，对疫苗的研制、生产、流通、预防接种全过程都提出了特别的制度和规定。同时对生产销售假劣疫苗等违法行为，设置了远比一般药品高的处罚，明确处罚到人，对违法者给予严厉的资格罚、财产罚和自由罚。

焦红强调，《疫苗管理法》兼顾安全、发展和创新。为积极地促进我国疫苗质量的进一步提升，《疫苗管理法》中作出一系列的新规来鼓励疫苗的创新和发展。

焦红指出，建国以来，特别是改革开放以来，我国疫苗产业取得了飞速发展，是世界上为数不多的能够依靠自身能力解决全部计划免疫疫苗的国家之一。我国曾于2011年和2014年两次通过了世界卫生组织的疫苗国家监管体系评估，当前正准备接受世界卫生组织新一轮评估。要以《疫苗管理法》出台为契机，全面改善我国药品和疫苗监管体系，强化监管能力，更好地服务疫苗产业发展，守护人民群众的用药安全，推动我国从疫苗大国迈向疫苗强国。

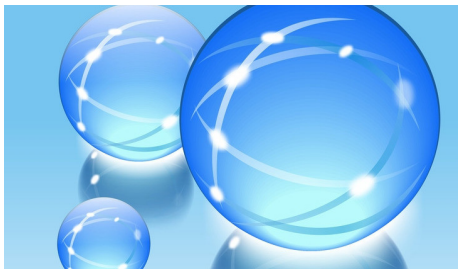
(2019-06-30)

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

NMPA Issued the Announcement on the Requirements for Dossiers and Samples for Verification and Inspection of Specifications for Overseas New Drugs Urgently Needed in Clinical Settings

To implement the requirements in the *Announcement on Issues Pertaining to the Review and Approval of Overseas New Drugs Urgently Needed in Clinical Settings* (No. 79 of 2018) and expedite the review & approval of overseas new marketed drugs urgently needed in clinical settings, NMPA organized the formulation of the *Requirements for Dossiers and Samples for Verification and Inspection of Specifications for Overseas New Drugs Urgently Needed in Clinical Settings (Chemicals)* and the *Requirements for Dossiers and Samples for Verification and Inspection of Specifications for Overseas New Drugs Urgently Needed in Clinical Settings (Biologicals)*, which were issued on June 25, 2019. For any variety included in the list of *Overseas New Drugs Urgently Needed in Clinical Settings* promulgated by CDE of NMPA, the applicant shall, while applying for marketing, submit the relevant dossiers and samples for drug standard verification and inspection to the National Institutes for Food and Drug Control in accordance with the requirements of this Announcement.

This Announcement shall enter into effect as the date of promulgation.



Annex 1 Requirements for Dossiers and Samples for Verification and Inspection of Specifications for Overseas New Drugs Urgently Needed in Clinical Settings (Chemicals)

I. Requirements for dossiers

1. The *Notice of Acceptance* (Photocopies) and the Notice of Inspection (Original) issued by Center for Drug Evaluation, and the *Application Form for Registration of Imported Drugs* (Photocopies) filled in by the applicant.
2. Drug substance release or shelf-life specifications in Chinese and English versions, test methods and relevant method validation data (including validation data for sterility and microbial limit tests in accordance with the current *Chinese Pharmacopoeia*), specifications and drafting instructions collated as per the format of the current *Chinese Pharmacopoeia*.
3. Prescription and production process.
4. Factory inspection report.
5. Test report and related research materials of standard substance (reference substance) involved in the specification.
6. Specifications, test methods and other dossiers for APIs and excipients in the preparations applied.
7. Stability test data.
8. Other necessary pharmaceutical research materials.

The above information must be provided with both a paper version (with the official seal of the applicant) and corresponding electronic version.

II. Requirements for samples, standard substances and test materials

(I) Samples

1. The sample should be of commercial production scale, and the sample-related information (such as place of origin, packaging materials) should

国家药品监督管理局发布《关于临床急需境外新药标准复核检验用资料及样品要求》的通告

为落实《关于临床急需境外新药审评审批相关事宜的公告》（2018年第79号）要求，加快临床急需境外上市新药审评审批，国家药品监督管理局组织制定了《临床急需境外新药标准复核检验用资料及样品要求（化学药品）》和《临床急需境外新药标准复核检验用资料及样品要求（生物制品）》，于2019年6月25日发布。凡列入国家药监局药品审评中心公布的《临床急需境外新药名单》的品种，申请人应当在申报药品上市时按照本通告要求同步向中国食品药品检定研究院提交用于药品标准复核检验的相关资料及样品。

本通告自发布之日起实施。

附件1. 临床急需境外新药标准复核检验用资料及样品要求（化学药品）

一、资料要求

1. 国家药品审评机构开具的《受理通知单》（复印件）和《检验通知单》（原件）及申请人填写的《进口药品注册申请表》（复印件）。

2. 出厂及货架期的中、英文药品标准，检验方法及相关检验方法的方法学验证资料（包括符合现行《中国药典》要求的无菌及微生物限度检查的验证资料），按照现行版《中国药典》格式整理的药品标准及起草说明。

3. 处方及生产工艺。

4. 出厂检验报告书。

5. 标准中涉及的标准物质（对照品）检验报告书及相关研究资料。

6. 申报制剂中的原料药和辅料的标准和检验方法等资料。

7. 稳定性试验资料。

8. 其他必要的药学研究资料。

以上资料需同时提供纸质版（加盖申请人公章）和相应电子版。

二、样品、标准物质及实验材料要求

（一）样品

1. 样品应该为商业化生产规模，样品相

be consistent with that provided when applying for marketing registration.

2. The sample APIs should be sub-packaged in advance, under proper conditions, with packaging materials consistent with those to be imported as applied. Small packaging specifications should be selected as far as possible to avoid sample contamination and ensure the proper progress of each test.

3. For a sample with various strengths, three batches of samples per strength, the sample size of each batch shall triple that of the full test. The shelf life of all samples should be no less than 6 months near expiry date. For liquid preparations, semi-solid preparations (such as ointments, creams) with identical concentration of the main drug and various strengths, three batches of the maximum strength and at least one batch of other strengths can be selected for test, as appropriate.

4. For specifications involving microbial limits, sterility and other test items, to avoid sample contamination, the individually packaged samples for this test shall also be provided.

(II) Standard substances

The standard substance (reference or standard product) involved in the test and method validation shall be provided in triplication to satisfy the standard verification and inspection and initial import inspection.

(III) Test materials

Test materials beyond those used in the current Chinese Pharmacopoeia, including excipients in preparations, special chromatographic columns, special reagents, and laboratory supplies, etc.

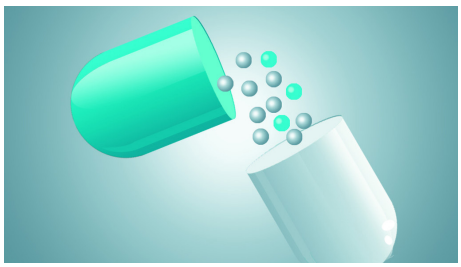
Annex 2 Requirements for Dossiers and Samples for Verification and Inspection of Specifications for Overseas New Drugs Urgently Needed in Clinical Settings (Biologicals)

I. Requirements for dossiers

1. The *Notice of Acceptance* (Photocopies) and the Notice of Inspection (Original) issued by Center for Drug Evaluation, and the *Application Form for Registration of Imported Drugs* (Photocopies) filled in by the applicant.

2. Raw liquid and finished product release or shelf-life specifications in Chinese and English versions, test methods and relevant method validation data (including validation data for sterility and microbial limit tests in accordance with the current *Chinese Pharmacopoeia*), specifications and drafting instructions collated as per the format of the current *Chinese Pharmacopoeia*.

3. Prescription and production process of raw liquid and finished product.



4. Inspection report of raw liquid and finished product.

5. Test report and related research materials of standard substance (reference substance or product) involved in the specification.

6. Specifications, test methods and other dossiers for APIs and excipients in the products applied.

7. Stability test data.

8. Other necessary pharmaceutical research materials.

The above information must be provided with both a paper version (with the official seal of the applicant) and corresponding

关信息（如产地、包装材料等）应与申请上市注册时提供的信息一致。

2. 原料药应提前在适当的条件下选用与申报进口包装材料一致的包装材料进行分装后送样，应尽量选取小的包装规格，避免样品污染，保证各项实验的进行。

3. 样品为多种规格的，每个规格为三批样品，每批样品量为全检量的三倍，样品的有效期应距有效期末一般不少于6个月。液体制剂、半固体制剂（如软膏、乳膏等）如主药浓度相同，存在有多种规格的，可根据具体情况确定一种规格的三批样品和其他规格至少一批样品进行检验。

4. 标准中涉及微生物限度、无菌等项目的，为避免样品污染，还应提供该用于该检验的独立包装样品。

（二）标准物质

提供检验及方法学验证所涉及的标准物质（对照品或标准品），为满足标准复核检验及首次进口检验用的三倍量。

（三）实验材料

超出现行版《中国药典》标准中使用的实验材料，包括制剂中的辅料、特殊色谱柱、特殊试剂、实验用品等。

附件2 临床急需境外新药标准复核检验用资料及样品要求（生物制品）

一、资料要求

1. 国家药品审评机构开具的《受理通知书》（复印件）和《检验通知单》（原件）及申请人填写的《进口药品注册申请表》（复印件）。

2. 原液和成品的出厂及货架期的中、英文药品标准、检验方法及相关检验方法的方法学验证资料（包括符合现行《中国药典》要求的无菌及微生物限度检查的验证资料）；按照现行版《中国药典》格式整理的药品标准及起草说明。

3. 原液和成品的处方及生产工艺。

4. 原液和成品的检验报告书。

5. 标准中涉及的标准物质（对照品或参比品）检验报告书及相关研究资料。

6. 申报产品中的原料药和辅料的标准和检验方法等资料。

7. 稳定性试验资料。

8. 其他必要的药学研究资料。

以上资料需同时提交纸质版（加盖申请

electronic version.

II. Requirements for samples, standard substances and test materials

(I) Samples

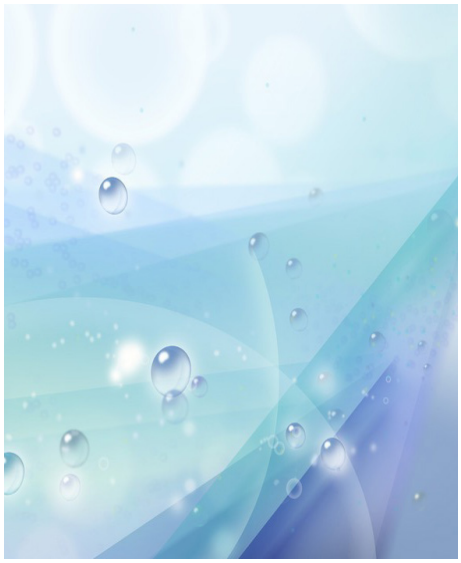
1. The sample should be of commercial production scale, and the sample-related information (such as place of origin, packaging materials) should be consistent with that provided when applying for marketing registration.
2. The raw liquid should be sub-packaged in advance, under proper conditions, with packaging materials consistent with those to be imported as applied. Small packaging specifications should be selected as far as possible to avoid sample contamination and ensure the proper progress of each test.
3. For a sample with various strengths, three batches of samples per strength, the sample size of each batch shall triple that of the full test. The shelf life of all samples should be no less than 6 months near expiry date. For liquid preparations, semi-solid preparations (such as ointments, creams) with identical concentration of the main drug and various strengths, three batches of the maximum strength and at least one batch of other strengths can be selected for test, as appropriate.
4. For specifications involving microbial limits, sterility and other test items, to avoid sample contamination, the individually packaged samples for this test shall also be provided.

(II) Standard substances

Standard substance (reference substance or product) shall have a sample size tripling that of the test amount for standard verification and inspection, and should be packaged in small size as much as possible.

(III) Test materials

Test materials beyond those used in the current Chinese Pharmacopoeia, including excipients in preparations, special chromatographic columns, special reagents, cell strains for assay, bacterial strains, and laboratory supplies, etc. (June 25, 2019)



人公章）和相应电子版。

二、样品、标准物质及实验材料要求

（一）样品

1.样品应该为商业化生产规模的样品，检验样品的相关信息（如产地、包装材料等）应与申请上市注册时提供的信息一致。

2. 原液应提前在适当的条件下选用合适的包装材料进行分装后送样，保证所用包装材料不影响产品质量，并尽量选取小的包装规格，避免样品的污染，保证各项实验的进行。

3. 样品为多种规格的，每个规格为三批样品，每批样品量为全检量的三倍，样品送检日期应距有效期末一般不少于6个月。成品如主药浓度相同，存在有多种规格的，应提供最大规格的三批样品和其他规格至少一批样品进行检验。

4. 标准中涉及微生物限度、无菌等项目的，为避免样品污染，还应提供该用于该检验的独立包装样品。

（二）标准物质

提供三倍检验用量的标准物质（对照品或参比品），用于标准复核检验，应尽量分装为小包装规格。

（三）实验材料

超出现行版《中国药典》标准中使用的实验材料，包括制剂中的辅料、特殊色谱柱、特殊试剂、检定用细胞株和菌毒种、实验用品等。 (2019-06-25)

NMPA Promulgated the *Guidelines for Clinical Safety Literature Evaluation of Marketed Drugs (Interim)*

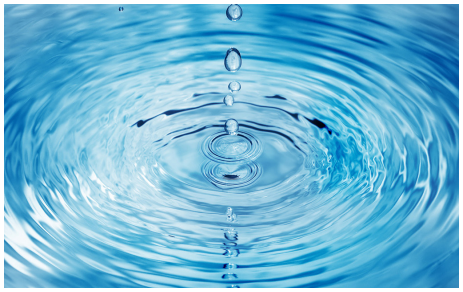
To further implement the principal responsibility of drug safety by drug Marketing Authorization Holders (including pharmaceutical manufacturing enterprise holding the drug approval proof documents, hereinafter referred to as the Holders), elevate the ability of the Holders to perform their duties, and regulate the holders to perform systematic review on clinical safety literature, NMPA organized the formulation of the *Guidelines for Clinical Safety Literature Evaluation of*

国家药品监督管理局发布《上市药品临床安全性文献评价指导原则（试行）》

为进一步落实药品上市许可持有人（包括持有药品批准证明文件的生产企业，以下简称持有人）药品安全主体责任，提升持有人履职能力，规范持有人开展临床安全性文献的系统评价，国家药品

Marketed Drugs (Interim), which was issued on June 18, 2019.

The Article 4 of the CNDA *Announcement on the Direct Reporting of Adverse Reactions by Marketing Authorization Holders* (No. 66 of 2018) stipulates that holders should regularly evaluate the ADR Monitoring data, clinical research, literature, etc. Clinical safety literature evaluation of marketed drugs, as one of the major methods for post-marketing clinical research, refers to the process of collection, as systematic and comprehensive as possible, of relevant clinical safety research literatures for specific marketed drugs within a certain time frame; the systematic screening, data extraction, quality evaluation, induction and collation of literature; and thence the qualitative or quantitative comprehensive analysis and evaluation, leading to the formation of evaluation reports. The basic elements of literature evaluation include the general process, methodological points, and written norms of evaluation report.



Drawing on the continuous updating concepts and methods of evidence-based medical evidence classification, grading, and rigorous evaluation, with reference to the indicators and forms of the comprehensive evaluation of health technology, the *Guidelines* introduces the standardized operation process and the whole process of quality control methods of Cochrane Systematic Review, aiming to provide guidance for drug Marketing Authorization Holders (hereinafter referred to as Holders) to carry out clinical safety literature evaluation and write related reports for marketed drugs (incl. TCM, chemicals and biologicals).

(June 18, 2019)

监督管理局组织制定了《上市药品临床安全性文献评价指导原则（试行）》，于2019年6月18日发布。

国家药品监督管理局《关于药品上市许可持有人直接报告不良反应事宜的公告》（2018年第66号）第四款规定，持有人应当定期对药品不良反应监测数据、临床研究、文献等资料进行评价。上市药品临床安全性文献评价作为药品上市后临床研究的主要方法之一，是指尽可能全面系统地收集一定时间范围内、特定上市药品的临床安全性研究相关文献，在对文献资料进行系统筛选、资料提取、质量评价和归纳整理的基础上，进行定性或定量综合分析评价，并形成评价报告的过程。基本要素包括文献评价的一般流程、方法学要点以及评价报告撰写规范。

本指导原则借鉴了循证医学证据分类、分级、严格评价和不断更新的理念与方法，参考了卫生技术评估综合评价卫生技术的指标与形式，引进了Cochrane系统评价规范化操作流程和全程质量控制的方法，旨在为药品上市许可持有人（以下简称持有人）开展上市药品（包括中药、化学药和生物制品）的临床安全性文献评价和撰写文献评价报告提供指导。

(2019-06-18)

NMPA Promulgated the *Technical Guidelines for Clinical Trial of Recombinant Human Coagulation Factor VIII* and the *Technical Guidelines for Clinical Trial of Recombinant Human Coagulation Factor IX*

To standardize and guide the implementation of clinical trials of recombinant human coagulation factor VIII and IX products, and promote the virtuous development of such products, NMPA organized the formulation of the *Technical Guidelines for Clinical Trial of Recombinant Human Coagulation Factor VIII* and the *Technical Guidelines for Clinical Trial of Recombinant Human Coagulation Factor IX*, which were issued on June 11, 2019.

(June 11, 2019)

国家药品监督管理局发布重组人凝血因子Ⅷ临床试验技术指导原则和重组人凝血因子Ⅸ临床试验技术指导原则

为规范和指导重组人凝血因子Ⅷ和重组人凝血因子Ⅸ制品临床试验的实施，促进该类制品的良性发展，国家药品监督管理局组织制定了《重组人凝血因子Ⅷ临床试验技术指导原则》和《重组人凝血因子Ⅸ临床试验技术指导原则》，于2019年6月11日发布。

(2019-06-11)

General Information

General Office of the State Council Issued the *Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System in 2019*

Recently, the General Office of the State Council issued the *Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System in 2019* (hereinafter referred to as the *Tasks*).

The *Tasks* pointed out that it is necessary to take Xi Jinping's Thought on Socialism with Chinese Characteristics for a New Era as the guide, comprehensively follow the policies set forth in the 19th National Party Congress, and the Second and Third Plenary Session of the 19th Party Central Committees, and conscientiously implement the decision-making and deployment of the Party Central Committee and the State Council on Healthy China Strategy and deepening the reform of the pharmaceutical and healthcare system. We will adhere to people-centered health development, to safeguarding basic health insurance, strengthening primary healthcare institutions, and constructing mechanisms covering the bidding and procurement system for essential drugs. Focusing on transforming the treatment-centered development model to a wellness-centered one, we will put prevention first, and reinforce disease prevention and health promotion. Regarding the solutions for low accessibility and high expenditure in health service, efforts shall be made to deepen the interlocked reform of health care, health insurance, and pharmaceuticals, and unswervingly promote the fruition and tangible benefits of healthcare reform for the people.

The *Tasks* clarified the key work areas of two aspects: 1. Documents to be formulated via research and deliberation, involving 15 documents related to Healthy China Actions; promoting the healthy and regulated development of non-governmental medical institutions; Drug List of welcomed generics; standardizing the use of medical consumables; furthering healthcare reform with the centralized procurement and use of drugs as a breakthrough; medication management in medical institutions; Internet-based diagnosis & treatment, payments and medical insurance reimbursement; reform of professional title system for health professional and technical personnel; establishment and improvement of the elderly healthcare system; performance evaluation of public health institutions at the Secondary and lower levels; strengthening the management of physician workforce; management of Medical Consortium; reform of the salary system of public hospitals; improvement of employees' medical insurance personal accounts, and supervision over the use of medical insurance funds. 2. Key tasks to be put into practice, involving 21 specific pursuits mainly focusing on addressing low accessibility and high expenditure in healthcare and strengthening hospital management, etc. To address low accessibility of healthcare, the pursuits proposed to promote the construction of national and regional medical centers; orderly develop medical consortia to promote Hierarchical Diagnosis & Treatment; deepen the reform of *Streamlining Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation* and *Optimizing Services* and support the running of medical institutions by social capital; facilitate the development of *Internet + health care*; coordinate and promote county-level comprehensive healthcare reform; implement Healthy China Action; and fortify the prevention and control of catastrophic diseases such as cancer. To address high expenditure in healthcare, the pursuits proposed to advance the pilots of State-led centralized drug procurement and use; promote the reform of high-value medical consumables; consolidate and improve the National Essential Drug System; carry forward the reform of medical insurance reimbursement models; improve the compensation mechanism of public hospitals; deepen the comprehensive reform of public hospitals; and actualize in-depth poverty

综合信息

国务院办公厅印发《深化医药卫生体制改革2019年重点工作任务》

近日，国务院办公厅印发《深化医药卫生体制改革2019年重点工作任务》（以下简称《任务》）。

《任务》指出，要以习近平新时代中国特色社会主义思想为指导，全面贯彻党的十九大和十九届二中、三中全会精神，认真落实党中央、国务院关于实施健康中国战略和深化医药卫生体制改革的决策部署，坚持以人民健康为中心，坚持保基本、强基层、建机制，紧紧围绕把以治病为中心转变为以人民健康为中心，落实预防为主，加强疾病预防和健康促进，紧紧围绕解决看病难、看病贵问题，深化医疗、医保、医药联动改革，坚定不移推动医改落地见效、惠及人民群众。

《任务》明确了两方面重点工作内容。一是要研究制定的文件，主要涉及健康中国行动、促进社会办医健康规范发展、鼓励仿制的药品目录、规范医用耗材使用、以药品集中采购和使用为突破口进一步深化医改、医疗机构用药管理、互联网诊疗收费和医保支付、卫生专业技术人员职称制度改革、建立完善老年健康服务体系、二级及以下公立医疗机构绩效考核、加强医生队伍管理、医联体管理、公立医院薪酬制度改革、改进职工医保个人账户、医疗保障基金使用监管等方面的15个文件。二是要推动落实的重点工作，主要围绕解决看病难看病贵问题和加强医院管理等方面，提出21项具体工作。解决看病难方面，提出推进国家医学中心和区域医疗中心建设、有序发展医联体促进分级诊疗、深化“放管服”改革支持社会办医、促进“互联网+医疗健康”发展、统筹推进县域综合医改、实施健康中国行动、加强癌症等重大疾病防治等重点工作。解决看病贵方面，提出推进国家组织药品集中采购和使用试点、推进高值医用耗材改革、巩固完善国家基本药物制度、推进医保支付方式改革、完善公立医院补偿机制、深化公立医院综合改革、深入实施健康扶贫等重点工作。加强医院管理方面，提出开展公立医院绩效考核、进一步改善医疗服务等重点工作。

《任务》强调，各地区、各有关部门

alleviation via healthcare. To strengthen hospital management, the pursuits proposed to unfold performance evaluation in public hospitals and further improve healthcare services, etc.

The *Tasks* emphasizes that all regions and relevant departments must earnestly strengthen leadership, take effective measures, be brave in taking responsibility and action, and complete tasks on time and in good quality. It is necessary to proactively and fully release information on reform policies, to promote experiences and build consensus on reform. The Tasks also clarified the responsible departments of various reform tasks and put forward time and schedule requirements for the policy documents that need to be formulated. (June 6, 2019)

要切实加强领导，采取有力措施，勇于担当作为，按时保质完成各项任务。要主动发布、充分释放改革政策信息，做好经验推广，凝聚改革共识。《任务》还明确了各项改革任务的负责部门，对需要制订的政策文件提出时间和进度要求。

(2019-06-06)

Special Column

2019 China Cancer Immunotherapy Workshop Successfully Held

2019 China Cancer Immunotherapy Workshop was successfully held on June 29-30, 2019 in Tianjin, China. The Workshop was organized by China Center for Food and Drug International Exchange(CCFDIE), in cooperation with the Center for Drug Evaluation(CDE) of National Medical Products Administration(NMPA), Chinese American Hematologist and Oncologist Network(CAHON) and School of Medicine Tsinghua University.

Focusing on the hot issues in the field of cancer immunotherapy, the Workshop set up 7 topics including Immune Resistance and Combination Therapy, Emerging New Immunotherapy, Perspective from Biopharma Industry, Clinical Update on Checkpoint Inhibitors, Clinical Update on Cellular Therapy and Regulatory Considerations.

In the Workshop, Dr. Ronald Levy, who is the Member of US National Academy of Sciences, Member of US National Academy of Medicine, professor of Stanford University, was specially invited to deliver a keynote speech entitled *In Situ Therapeutic Vaccination* and share the experience and views on clinical research progress. Prof. Lieping Chen of Yale University, Prof. Xuetao Cao of Nankai University, Prof. Yilong Wu, Prof. Jun Zhu and other famous experts also shared their latest achievements in the field of cancer immunotherapy and put forward their views from the perspective of clinical research and patient needs.

More than 50 Chinese and foreign leading experts in the field of cancer immunotherapy, including US FDA, EMA, CDE, CAHON delivered speeches on the current status and hot topics of cancer immunotherapy and interactively communicated with the participants.

The China Cancer Immunotherapy Workshop has been successfully held for five consecutive years with rising social attention and influence. The Workshop has provided an important academic exchange platform for Chinese and foreign drug regulatory authorities, academia and industry, promoting the exchange of professional knowledge and experience in the field of cancer immunotherapy. It has played a positive role in promoting international exchanges and cooperation in the field of drug regulation and enhancing innovation and development in the field of cancer immunotherapy.

(July 04, 2019)

专栏

2019中国肿瘤免疫治疗会议成功举办

2019年6月29日至6月30日，由中国食品药品国际交流中心 (CCFDIE) 主办，药品审评中心 (CDE)、美国华裔血液及肿瘤专家学会 (CAHON) 和清华大学医学院协办的2019中国肿瘤免疫治疗会议在天津成功举办。

会议围绕肿瘤免疫治疗领域热点问题设置了免疫耐药和联合疗法、肿瘤免疫新型疗法、生物制药界视角——研发者说、检查点抑制剂的临床治疗进展、细胞疗法的临床进展、监管考量等7个专题。

本次会议特别邀请了美国国家科学院院士、美国国家医学院院士、斯坦福大学罗纳德·莱维 (Ronald Levy) 教授，发表了题为“原位治疗性疫苗”的主旨演讲，分享了原位治疗性疫苗临床研究进展等方面的经验与看法。耶鲁大学陈列平教授、南开大学校长曹雪涛院士、我国著名肿瘤领域专家吴一龙教授、朱军教授等也分享了肿瘤免疫治疗领域的最新成果，从临床研究和患者需求的角度提出了观点和经验。

美国FDA、欧盟药品监管机构、国家药品监督管理局药品审评中心、美国华裔血液及肿瘤专家学会等50余位中外肿瘤免疫治疗学术界顶尖专家针对当前肿瘤免疫治疗的现状和热点进行演讲，并与参会代表进行互动交流。

中国肿瘤免疫治疗会议已连续成功举办了5届，社会关注度和影响力不断扩大，会议为中外药品监管机构、学术界、企业界搭建了一个重要学术交流平台，促进了肿瘤免疫治疗领域的专业知识和经验交流，为推动我国药品监管领域的国际交流合作和肿瘤免疫治疗领域创新发展发挥了积极的作用。

(2019-07-04)

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

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China Center for Food and Drug International Exchange (CCFDIE)
中国食品药品国际交流中心

Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, P.R.C.
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编：100082

Tel: 010-8221 2866 Fax: 010-8221 2857
Email: ccfdie@ccfdie.org
Website: www.ccfdie.org

Servier (Tianjin) Pharmaceutical Co., Ltd.
施维雅（天津）制药有限公司

Address: 6 Floor, West Building, World Financial Center, No.1, East 3rd Ring Middle Road, Chaoyang District, 100020 Beijing, China
北京市朝阳区东三环中路1号环球金融中心西楼6层
邮编：100020

Tel: 010-6561 0341
Fax: 010-6561 0348
Website: www.servier.com.cn