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SFDA Requires to Regulate the Production and Distribution of Traditional Chinese Medicine and Severely Crack down on Illegal Activities

In order to regulate the production and distribution of traditional Chinese medicine (TCM), severely crack down on illegal activities, and effectively strengthen supervision to ensure the quality of TCM, on July 18, 2012, SFDA issued the "Notice on Regulating the Production and Distribution of Traditional Chinese Medicine and Severely Cracking down on Illegal Activities" to clarify relevant requirements.

The "Notice" requires to regulate the production and distribution of traditional Chinese medicine and Severely crack down on illegal activities, resolutely investigate and punish illegal activities of producing and selling counterfeit drugs, and illegal activities in the Chinese medicinal herbs market, the production process of proprietary Chinese medicines and Chinese Herbal Medicine as well as in the circulation and use of Chinese Herbal Medicine. Food and drug administration departments of all levels shall enhance their ideological understanding, strengthen the organization and leadership, reinforce supervision and inspection, intensify the investigation and handling of such cases, and supervise the enterprises' strict implementation of the GMP and GSP. (July 24, 2012)

国家食品药品监督管理局要求规范中药生产经营秩序严厉查处违法违规行为

为规范中药生产经营秩序，严厉查处违法违规行为，切实加强监管，确保中药质量，2012年7月18日，国家食品药品监督管理局印发《关于规范中药生产经营秩序严厉查处违法违规行为的通知》，就有关要求作出明确。

《通知》要求，要加强监督管理规范中药生产经营秩序，坚决查处制假售假等违法违规行为，严厉查处中药材专业市场违法违规行为、中成药生产过程中的违法违规行为、中药饮片生产过程中的违法违规行为和中药饮片流通使用环节的违法违规行为。要提高思想认识，加强组织领导，加大监督检查和监督检验力度，加强案件查办工作，监督企业严格执行药品GMP和GSP。（2012年07月24日）

2012 National Drug Safety Supervision Work Conference Convened

The National Drug Safety Supervision Work Conference was convened between July 17 2012 and July 19 2012. SFDA Deputy Commissioner Wu Zhen attended the meeting.

The Conference conveyed the spirit of the National Work Conference on Food and Drug Supervision and Management, analyzed the situation and tasks for current drug safety supervision. The food and drug administration of 31 provinces, autonomous regions, and municipalities and Xinjiang production and construction corps attended the meeting and researched & discussed related works, and made deployments to further strengthen drug safety supervision.

(July 22, 2012)

2012年全国药品安全监管工作座谈会召开

2012年7月17至19日，全国药品安全监管工作座谈会召开。国家食品药品监督管理局副局长吴浈出席会议。

会议传达了全国食品药品监管工作座谈会议精神，分析了当前药品安全监管工作面临的形势和任务，对药品安全监管工作进行了研究、讨论，并对进一步加强药品安全监管工作进行了部署。 来自全国31个省、自治区、直辖市和新疆生产建设兵团食品药品监督管理局的代表出席了会议。（2012年7月22日）

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Event Brief

A publicity week named "Health of you and me starts from safe medication use on" Launched in Xining City

On July 24, 2012, the publicity week named "Health of you and me starts from safe medication use on", which was sponsored by the National Center for ADR Monitoring, co-sponsored by Qinghai Food and Drug Administration, and jointly hosted by ADR Monitoring Center of Qinghai Province and Food and Drug Administration of Xining City, officially started in Xining market, Qinghai Province.

In the Activity, which is a China / WHO technical cooperation project in 2012 - 2013, the National Center for ADR Monitoring will carry out Medication Safety Awareness Week activities in three regions of Xinjiang, Qinghai and Tibet for primary health care personnel and the public, to popularize the knowledge for Adverse Drug Reaction, improve the drug safety awareness of medical staff of key Western provinces and the public, and promote Adverse Drug Reaction Monitoring in the western provinces.

Relevant leaders of the SFDA International Cooperation Department and Drug Safety Supervision Department, the National Center for ADR Monitoring, Qinghai Province Political Consultative Conference, Qinghai People's Congress, Health Department, and Food and Drug Administration attended the launching ceremony. (July 28, 2012)

活动报道

"安全用药、健康你我"宣传周活动在西宁市启动

2012年7月24日，在青海省西宁市场，由国家药品不良反应监测中心主办、青海省食品药品监管局协办、青海省药品不良反应监测中心、西宁市食品药品监管局承办的"安全用药，健康你我"主题安全用药宣传周活动正式启动。

作为2012—2013年度中国/世界卫生组织技术合作项目，在活动中，国家药品不良反应监测中心将在新疆、青海、西藏3个地区开展面向基层医护人员、公众的安全用药宣传周活动，普及药品不良反应知识，提高西部重点省份医务人员和公众的药品安全意识，推动西部省份药品不良反应监测工作。

国家食品药品监管局国际合作司、药品安全监管司、国家药品不良反应监测中心以及青海省政协、人大、省卫生厅、省食品药品监管局的相关负责人出席了启动式。

（2012年7月28日）

"Quality Management Practice for the Communication and Exchange between the Applicants for Registration Application and CDE" issued by CDE

On July 16, 2012, CDE of SFDA issued the Quality Management Practice for the Communication between the Applicants for Registration Application and CDE (Interim). The Practice is designed to promote the science of evaluation and reduce the risks of decision-making by means of improving the quality and efficiency of communication and exchange.

Chapter I General Provisions

Article 1 In order to further facilitate the communication and exchange of Center between Drug Evaluation (hereinafter referred to as CDE) and the applicants for registration application (hereinafter referred to as the Applicants), enhance the openness and transparency therein, regulate the management of related works, and improve the level and quality of the management and decision-making for drug technical review, we hereby develop this Practice.

Article 2 CDE's communication and exchange with the Applicants generally can be divided into the following patterns:

(A) Two-Way Appointment-Based Communication;

(B) Query-Based Communication;

(C) Q & A-Based Communication;

(D) Open-Day Communication.

Article 3 On the basis of summing up previous communication experience of CDE with the Applicants, and related normative documents, and taking into account the status quo of China's drug review and drug R&D, this Practice is developed in the principle of enhancing the communication quality and efficiency, and serving for drug R & D, innovation and

药品审评中心发布《药品审评中心与注册申请人沟通交流质量管理规范（试行）》

2012年7月16日，国家食品药品监督管理局药品审评中心发布《药品审评中心与注册申请人沟通交流质量管理规范（试行）》。制定本规范目的是通过提高沟通交流的质量与效率，促进审评决策的科学性，降低决策的风险。

第一章 总则

一、为进一步加强药品审评中心（以下简称药审中心）与注册申请人（以下简称申请人）的沟通交流，不断加大公开透明力度，规范相关工作管理，提高药品技术审评管理与决策的水平和质量，制定本规范。

二、药审中心与申请人的沟通交流一般可分为以下几种类型：

（一）双向预约式沟通交流；

（二）查询式沟通交流；

（三）问询式沟通交流；

（四）开放式沟通交流。

三、本规范是在梳理总结药审中心和申请人既往沟通交流经验和相关规范化文件的基础上，结合当前我国药品技术审评

technical review.

Article 4 This Practice has elaborated the classification, organization procedures and requirements for communication between the CDE and the Applicants, for any discrepancies of previous CDE normative documents with this Practice, the provisions of this Practice shall prevail.

Chapter II Two-Way Appointment-Based Communication

Article 5 In Two-Way Appointment-Based Communication, either party of CDE and the Applicants can make an appointment in advance and in specific manner.

Article 6 Two-Way Appointment-Based Communication aims to encourage innovation and supply of drugs urgently needed in clinical practice. It applies to the following circumstances: when the Applicants encounter critical or major technical problems in the key stages of drug R&D and need to communicate with CDE; or when CDE needs to communicate with the Applicants to improve the quality & efficiency and reduce the risks of decision-making in the technical drug review process.

Article 7 To ensure the quality and efficiency of communication, the proposing party shall make an appointment sufficiently in advance, so that the other party can get fully prepared for preliminary research, information collection, analysis, and evaluation etc.

Article 8 Two-Way Appointment-Based Communication can be proposed via the corresponding Section of the CDE Website, official correspondence, telephone, e-mail and other means.

Article 9 Two-Way Appointment-Based Communication is generally held in a conference, including face-to-face meetings, video and telephone conferences.

Article 10 Two-Way Appointment-Based Communication applications can be divided into the following five types according to the variety research process and the different stages of registration application.

(A) Pre-IND application -applied at the stage where non-clinical trials have been basically completed, but the clinical research has not yet been applied;

(B) IND application - applied at the stage where clinical research has been applied;

(C) End of phase I Application - applied at the stage where clinical research has been approved, and phase I clinical study phase has been completed;

(D) End of phase Ⅱ Application - applied at the stage where clinical research has been approved, and phase II clinical study phase has been completed;

(E) NDA Application - applied at the stage where clinical research has been approved, and production registration has been applied.

Article 11 The organization and management of Two-Way Appointment-Based Communication, according to different classifications of the appointment application, are regulated as follows:

(A) For the "A, C, D" (i.e., the Pre-IND, the End of phase I and the End of phase II) applications as stated in Article 10, the Operation Management Department, in conjunction with the relevant Review Departments, shall provide preliminary opinions to decide, after the approval of CDE leadership, the approval of appointment application and the departments responsible for the organization of communication meetings, who shall take charge of the organization and convening of meetings, the record of meeting minutes and other related works.

(B) The "B, E" (i.e., the IND and NDA) applications as stated in Article 10, i.e., the communication applications for varieties under CDE review, shall be reviewed and

和药品研发面临的现状，本着提升沟通交流质量和效率，服务于药品研发创新和技术审评的原则而制定。

四、本规范对药审中心与申请人之间沟通交流的分类、组织程序和要求等进行了明确，对于既往药审中心相关规范化文件与本规范表述等不尽一致之处，参照本规范执行。

第二章 双向预约式沟通交流

五、双向预约式沟通交流系指药审中心和申请人中的一方提前一定时间以特定的方式提出预约后进行的一种沟通交流。

六、双向预约式沟通交流为基于鼓励创新和解决临床急需用药的沟通交流。其适用于申请人在药品研发的关键阶段遇到关键或重大技术问题时，需要和药审中心进行沟通交流的情形；也适用于药审中心在药品技术审评过程中，为提升决策质量和效率，降低决策风险，需要与申请人进行沟通交流的情形。

七、为保证沟通交流的质量和效率，提出预约的一方应提前足够的时间提出预约，以便对方做好充分的前期调研、信息采集、分析、评估等工作。

八、双向预约式沟通交流可通过药审中心网站相应栏目、公函等途径提出。

九、双向预约式沟通交流一般以会议方式进行，具体包括面对面会议、视频会议和电话会议等。

十、双向预约式沟通交流申请，根据品种研究进程和注册申请的不同阶段可分为以下五种类型。

1. 临床前（Pre-IND）申请—基本完成非临床试验研究，但尚未提出临床研究申请阶段的申请；

2. 临床（IND）申请——已提出临床研究申请阶段的申请；

3. 完成I期临床后（End of phase I）申请——已批准进行临床研究，并已经完成I期临床研究阶段的申请；

4. 完成Ⅱ期临床后（End of phase Ⅱ）申请——已批准进行临床研究，并已完成Ⅱ期临床研究阶段的申请；

5. 生产（NDA）申请——完成临床研究，并提出生产注册申请阶段的申请。

十一、双向预约式沟通交流的组织管理，根据预约申请的不同分类，将申请和组织实施程序规定如下：

（一）针对本规范"第十项下第1、3、4"三类申请（即Pre-IND申请、End of phase I申请和End of phase Ⅱ），其预约申

approved by specific authorizer according to the decision-making pathway issued or issued under the authority of the CDE technical review report, and the opinions of relevant Review Departments; the organization and convening of meetings, the record of meeting minutes and other related works shall be under the care of Principal Reporting Department for the specific drug variety.

(C) The responsible departments for communication meetings shall be classified according to the different patterns of appointment applications as follows:

1. The “A, B, C” (i.e., the Pre-IND, the IND, the End of phase I) applications as stated in Article 10 shall be handled by the Pharmacology & Toxicology Department, the Clinical Department for the review of corresponding indications and the Pharmacy Department shall actively cooperate.
2. The “D, E” (i.e., the End of phase Ⅱ and NDA) applications as stated in Article 10 shall be handled by the Clinical Department for the review of corresponding indications, the Pharmacology & Toxicology Department and Pharmacy Department shall actively cooperate.

Article 12 In order to ensure the quality and efficiency of the Appointment-Based Communication meeting, the Two-Way Communication requests the proposing party to conduct adequate research, evidence collection, analysis, evaluation, etc. and to clarify the issues to be discussed, the indispensable attendees and other premises before the meeting, prior to applying for the appointment. The specific requirements for the appointment applications of varieties under or NOT under CDE review, are as follows:

(A) Two-Way Appointment-Based Communication for varieties under CDE review ---- Applicants’ proposal

1. The Applicants can apply for communication in a timely manner in light of the review progress and sequence of varieties publicized by the CDE website (www.cde.org.cn). The Applicants should provide detailed research information according to the overall research and evaluation of the specific variety, to clarify the issues to be discussed, the responsibilities and duties of the attendees, and submit these information to CDE via the "Applicants' Window" Section of CDE Website, or in official documents.
2. Upon receipt of the Applicants’ appointment applications, CDE shall designate Principal Reporting Department responsible for the specific variety to reply to the Applicants via the "Applicants’ Window" in about one month before the beginning of the review. Upon approval, the communication meeting shall be convened in about a week before the beginning of the drug variety review.
3. The reasons for disapproval of communication meetings shall be clearly stated in the reply information to the Applicants. The approval of communication meetings shall be conveyed to the Applicants with detailed description of the issues to be discussed, the materials to be submitted, the requirements for the attendees of both parties, and the time schedule and venue of the meeting, etc.

请的审批、负责组织沟通交流会议的部门等，由业务管理部会同相应审评部门提出初步意见，经中心领导审核批准后确定。负责沟通交流会议的部门负责组织召开会议、撰写会议纪要等相关工作。

（二）针对本规范“第十项下第2、5”二类申请（即IND申请和NDA申请），也即处于中心正在审评品种的沟通交流，将根据中心技术审评决策过程中技术审评报告授权签发的决策路径，其预约申请的审批、由具体授权签发人在征求相应审评部门意见的基础上审核批准；其沟通交流会议的组织落实、会议纪要的撰写等相关工作，由该品种主审报告部门具体负责。

（三）沟通交流会议的负责部门，根据预约申请的不同分类界定如下：

1. 本规范“第十项下第1、2、3”三类申请（即Pre-IND申请、IND申请、End of phase I申请）一般由药理毒理学部负责，相应适应症审评的临床部门、药学部门配合做好相关工作。

2. 本规范“第十项下第4、5”两类申请（即End of phase Ⅱ申请和NDA申请）由相应适应症审评的临床部门负责，药理毒理学部、药学部门配合做好相关工作。

十二、为保证预约式沟通交流会议的质量与效率，双向预约式沟通交流要求提出预约申请的一方，在会前做好充分的调研、采信、分析、评估等工作，明确拟沟通交流的问题，会议需要的资料、会议必须参加的人员等前提下，提出预约申请。根据预约申请涉及品种是否属于中心在审品种，具体要求如下：

（一）在审品种的双向预约式沟通交流——申请人提出

1. 申请人可根据药审中心网站（www.cde.org.cn）公示的品种审评进度和序列情况，适时提出沟通交流申请。申请人应根据该品种整体研究和评价情况，提供详细研究资料，明确拟沟通交流的问题，参加会议人员承担工作及职务等相关信息，通过药审中心网站“申请人之窗”栏目，或者以公文形式提交药审中心。

2. 药审中心在收到申请人提出的预约申请后，由负责具体品种的主审报告部门，结合品种审评计划，于品种开始审评前1个月左右，通过“申请人之窗”回复申请人。对于同意召开沟通交流会议的申请，应于品种开始审评前一周左右，组织安排会议。

3. 对于不同意召开沟通交流会议的申请，回复申请人信息应明确不同意召开沟通交流会议的理由。对于同意召开沟通会议的

4. The specific Department in charge shall be responsible to notify/ inform CDE participants, related coordinators of the Operation Management Department, Directors and Deputy Directors, competent CDE leaders etc. of the relevant meeting schedules and requirements via mails/SMS.

(B) Two-Way Appointment-Based Communication for varieties under review ---- proposed by CDE

1. According to the CDE decision-making pathway, in the decision-making process of the technical review, the professional principal reviewer/principal review reporter / directors of each review Department / CDE leaders can apply for communication in different stages of drug variety professional review, principal review reporters' comprehensive review or technical review.
2. The communication application should clarify the issues to be discussed, the materials to be submitted, the requirements for the attendees of the both parties, the time schedule and venue of the meeting and other information, which are to be submitted via CDE conference system, and shall be implemented by related review departments after approved by appropriate review procedures.
3. The specific departments in charge shall organize and arrange the communication meeting as soon as possible upon receipt of the CDE instructions, and feedback the issues to be discussed, the materials to be submitted, the requirements for the attendees of both parties, time schedule and venue of the meeting and related matters to the Applicants through the "Applicants' Window"; and shall be responsible to notify/ inform CDE participants, related coordinators of the Operation Management Department, Directors and Deputy Directors, competent CDE leaders etc. of the relevant meeting schedules and requirements via mails/SMS.

(C) Two-Way Appointment-Based Communication for varieties NOT under CDE review.

1. Under such cases, the communication is generally proposed by the Applicants.
2. The Applicants should provide detailed research information according to the overall research and evaluation of the specific variety, to clarify the issues to be discussed, the responsibilities and duties of the attendees, and submitted these information to CDE via the "Applicants' Window" Section of CDE Website, or in official documents.
3. The Applicants should make an appointment sufficiently in advance, so that relevant CDE personnel can hold adequate discussion and research on the research data submitted by the applicants, so as to ensure the quality and efficiency of communication.
4. Upon receipt of the Applicants' appointment applications, CDE shall designate specific department to reply to the Applicants via the "Applicants' Window" within 2 month according to CDE instructions. Upon approval, the communication meeting shall be convened within one month after the reply to the Applicants.
5. The requirements for the reply to Applicants and notifying / informing the relevant staff are identical with the corresponding provision of "Two-Way Appointment-Based Communication of varieties under review" in this Practice.

(D) The specific departments in charge are responsible for good preparations of communication meeting; they shall held adequate communication with the Applicants during the meeting, to reach consensus on the issues to be discussed and / or mutual understanding of the logic of the

申请，回复申请人信息应明确拟讨论的问题、会议需要提交的资料、双方参加会议人员需求，以及会议时间、会议地点等。

4. 具体负责部门负责将相关会议安排和要求以邮件方式通知/告知中心参加会议人员，业务管理部相关协调员、正副部长、分管中心领导等。

（二）在审品种的双向预约式沟通交流——药审中心提出

1. 根据药审中心技术审评决策路径，在技术审评决策过程中，专业主审人员/主审报告人/各审评部部长/中心领导，可在品种专业审评、主审报告人综合审评或技术审核等不同阶段提出沟通交流申请。

2. 沟通交流申请应明确拟讨论的问题、会议需要提交的资料、双方参加会议人员需求，拟定会议时间、会议地点等相关信息，通过中心会议系统提交，经相应审核程序批准后，由相应审评部门具体负责组织实施。

3. 具体负责部门应于中心批示后尽快组织安排沟通交流会议，并将会议需要讨论的问题、会议需要提交的资料、双方参加会议人员需求，以及会议时间、会议地点等相关事宜，通过“申请人之窗”反馈申请人；负责将相关会议安排和要求以邮件/短信方式通知/告知我中心参加会议人员，业务管理部相关协调员、正副部长、分管中心领导等。

（三）非在审品种的双向预约式沟通交流

1. 此类情况下的沟通交流一般由申请人提出。

2. 申请人应根据该品种整体研究和评价情况，提供详细研究资料，明确拟沟通交流的问题，参加会议人员承担工作及职务等相关信息，通过药审中心网站“申请人之窗”栏目，或者以公文形式提交药审中心。

3. 申请人应提前足够的时间提出预约申请，以便药审中心相关人员对申请人提交的研究资料进行充分的讨论和研究，以保证沟通交流的质量与效率。

4. 药审中心在收到申请人提出的预约申请后，由具体负责部门在2个月内，根据中心批示情况，通过“申请人之窗”回复申请人。对于同意召开沟通交流会议的申请，在回复申请人后的一个月内，组织安排会议。

5. 对于回复申请人和通知/告知药审中心相关人员的内容要求，同本规范“在审品种的双向预约式沟通交流”项下相应内容。

（四）具体负责部门负责做好沟通交流会议的会前准备；会议期间与申请人进行充分的沟通交流，就会议讨论问题应达成共识和/或双方互为了解辨析问题的逻辑和举证观点的证据等，以保证沟通交流的质量与效率。

analysis, and the presentation of evidence and opinions etc., so as to ensure the quality and efficiency of communication.

(E) The specific departments in charge shall record the meeting minutes, which should accurately reflect the procedures, major issues and realization of expected goals of the meetings.

The meeting minutes of drug varieties under CDE review shall be drafted by professional principal reviewer /principal review reporter, and submitted along with the technical review report to the Director of corresponding review department, minutes involving major decisions should be reported in accordance with the "Good Practice for Technical Review Decision Making Pathways of CDE (Interim)". The evidence material adopted in the meeting process, the meeting information etc. can be brought into the next stage of review consultation meetings or supplementary data according to the review of specific varieties, and if necessary, can be received and archived after corresponding approval procedures in accordance with relevant CDE regulations.

The meeting minutes of drug varieties NOT under CDE review shall be jointly drafted by the Applicants and personnel designated by the organizing department of the meeting, and confirmed by signatures (for CDE, the signature of the Director of the organizing department)/ seals of both parties after opinion-solicitation and basic consensus, and shall be handed out as a feedback to the attendees of both parties.

The Minutes of meetings shall be established and saved in the CDE conference system along with the conference application, relevant instructions, meeting schedules and other information, for CDE's reference and use in the follow-up research and review of related varieties, and also can be publicized to the public regularly regarding the contents of the Minutes.

(F) The specific departments in charge shall, in line with the meeting discussions, propose the handling suggestions for related varieties in a timely manner. The important conclusive information of the Meeting Minutes should be reflected in the technical review report.

Chapter III Query-Based Communication

Article 13 In Query-Based Communication, the Applicants can have access to the required information via CDE website (www.cde.org.cn).

Article 14 CDE Website provides information related to the application for drug registration and review, in a timely and user friendly manner for the Applicants' inquiry. The Specific information categories for query are as follows:

1. News category information: including the daily work updates, news focus, highlights and other information.
2. Technical guidance information: including related laws and regulations, technical requirements, electronic publications, guiding principles, and other information.
3. CDE publicly available information: on CDE functions, organization, human resources, etc.; public notification of varieties and sequences under review, the reviewers, the task & plan, progress, comments and conclusions of the review and other information; Overview of the review & evaluation of innovative drugs, the answers for common

（五）具体负责部门负责会后形成会议纪要，会议纪要应准确、全面地反映会议过程、主要讨论内容和会议预期目标的实现情况。

对于中心在审评品种，会议纪要由专业主审人/主审报告人负责起草，并随技术审评报告一起提交所在审评部部长，涉及重大决策的纪要还应按《药品审评中心技术审评决策路径管理规范（试行）》的要求进行报告。会议过程中采纳的佐证性资料、会议情况信息等，可根据具体品种的审评情况，带入下阶段审评咨询会议或发补内容中，必要时也可根据中心相关管理规定，履行相应审批程序后，予以接收，存档。

对于非中心在审品种，会议纪要由负责组织会议部门指定人员和申请人共同负责起草，并经征求双方参加会议人员意见，基本达成共识后，经双方（药审中心为组织会议部门部长）签字/公章确认后，分别反馈申请人和药审中心参加会议人员。

会议纪要应随会议申请和相关批示、会议安排等信息，在中心会议系统中建立并保存，以便供中心在后续相关品种的研究及审评中参考和利用，也可视会议纪要内容情况定期向申请人公开。

（六）具体负责部门负责根据会议讨论情况，会后及时形成相关品种的处理意见。会议纪要的重要结论性信息应在技术审评报告中予以体现。

第三章 查询式沟通交流

十三、查询式沟通交流系指通过药审中心网站（www.cde.org.cn）获得所需信息的一种沟通交流方式。

十四、药审中心网站提供与药品注册申请、药品审评相关的信息，以便于申请人能及时、便捷地查询。具体可供查询的主要信息如下：

（一）新闻类信息：包括日常工作动态，重点新闻、要闻等信息。

（二）技术指导类信息：包括相关法规要求、技术要求、电子刊物、指导原则等信息。

（三）药审中心公开发布信息：包括中心职能、组织机构、人力资源等情况；在审品种受理及序列公示、审评人员公示、审评任务计划、审评进度、审评意见、审评结论等信息；创新药审评评价概述、共性问题解答等信息；以及本规范所述申请人与药审中心沟通交流的申请、审批及组织落实情况等信息。

（四）数据库类信息：包括已上市品种数据库、已上市品种说明书数据库、常用

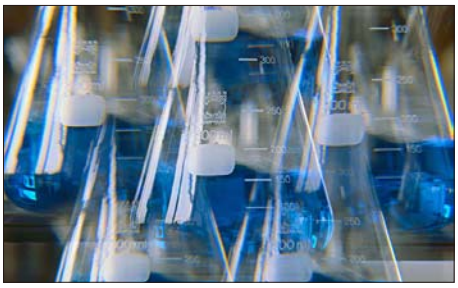
questions and other information; and the application, approval, organization and implementation of CDE's communication with the Applicants etc.

4. Database information: including the database of marketed varieties, database of the instructions (insert sheets) of marketed varieties, database of commonly used excipients, adverse drug reaction reports and other information.
5. Communication information: including the organization of CDE Open-Days and seminars, meetings and other information.

Article 15 The Applicants can avail of CDE Website to surf the news, the public notification of review plans & sequences, electronic publications, guidelines, overview of the review and evaluation of innovative drugs, the answers to common questions, as well as the public information related to the daily work and special work of CDE.

Article 16 In order to ensure the security of the Applicants' registration information, and enhance the openness of Applicants-related information, CDE shall provide more open and abundant drug technical review & evaluation information on the basis of real-name verification between CDE and the Applicants, through the "Applicants' Window", which can establish a more convenient and efficient CDE-Applicant two-way communication.

Article 17 Through the "Applicants' Window", CDE can publicize the specific review progress of registration application, reviewers, review reports, review conclusions and other information.



Article 18 Via the "Applicants' Window", the Applicants can submit electronic documents related to the application for drug registration, such as the summary/ overview of related research information, the manufacturing processes, specification, packaging insert etc.

Article 19 CDE website should apply advanced and appropriate search engines to provide full-text search service, and also timely update the information of the website, improve and perfect the website features, to facilitate the Applicants' timely and quick inquiry and access to the accurate and relevant information catering to their needs.

Article 20 While surfing the CDE Website, the Applicants could as well propose suggestions for CDE's continuous improvements of website functions to better serve the majority of registered Applicants.

Chapter Q & A-Based Communication

Article 21 In Q & A-Based Communication, the Applicants communicate with CDE on general technical issues through CDE website feedback, telephone, e-mail and other ways. This pattern of communication usually does not touch upon major decision making issues in the technical review process. Being a two-way communication model between CDE and the Applicants, it is divided into two categories of Applicants Q&A and CDE Q&A.

Article 22 Applicants Q&A are the inquiries made by the Applicants to CDE. Applicants Q&A can be proposed through the CDE Website (hereinafter referred to as the "Network") or by telephone.

(A) Network Q&A:

1. CDE website provides the "Information Feedback" for the Applicants to realize network inquiry.
2. While receiving the Applicants'

辅料数据库、药品不良反应报道等信息。

（五）交流工作信息：包括药审中心开放日组织情况、研讨班组织情况及相关会议情况等信息。

十五、申请人通过药审中心网站，可查询新闻、审评计划序列公示、电子刊物、指导原则、创新药审评评价概述、共性问题解答等，以及与中心各项日常工作、专项工作等有关的公共信息。

十六、为保证申请人注册信息的安全，同时也便于加大对申请人相关信息的公开力度，在药审中心与申请人之间建立实名验证的基础上，药审中心将通过"申请人之窗"公开更丰富的药品技术审评评价信息；通过"申请人之窗"还可与申请人之间建立更为便捷、高效的沟通交流。

十七、药审中心通过"申请人之窗"，公示注册申请的具体审评进度、审评人员、审评报告、审评结论等信息。

十八、申请人通过"申请人之窗"，可提交与药品注册申请相关的电子文件，如相关研究资料的综述性文件，生产工艺、质量标准、说明书等文件。

十九、药审中心网站应采用先进的、适宜的搜索引擎，提供全文检索服务功能，同时应及时更新网站信息，改进完善网站功能，以便申请人能及时、快速地通过查询获知其需要的、准确的相关信息。

二十、申请人可在使用过程中对药审中心网站提出改进建议，以便药审中心不断完善网站功能，更好地服务于广大注册申请人。

第四章 问询式沟通交流

二十一、问询式沟通交流系指申请人和药审中心之间通过药审中心网站信息反馈、电话、电子邮件等方式就一般性技术问题进行交流的沟通方式。该沟通方式通常不就技术审评过程中的重大决策性问题进行讨论。问询式沟通交流是药审中心和申请人之间的双向式沟通交流模式，包括申请人问询和中心问询两类。

二十二、申请人问询是指申请人向中心提出的问询。申请人问询可通过药审中心网站（以下简称"网络"）或电话方式提出。

（一）网络问询方式：

1. 药审中心网站提供"信息反馈"栏目，供申请人实现网络问询。

2. 在接受申请人信息反馈时，药审中心网站会给申请人提示，提示申请人在提出网络问询前应先查询共性问题解答、电子刊物等相应内容，以避免重复问题或同类问题等的问询。

feedback, CDE website will give prompts to the Applicants to check relevant information such as the answers for common problems and electronic publications prior to network inquiries, in order to avoid repeated questions or questions on similar problems.

3. CDE performs unified management on the "Information Feedback" submitted by the Applicants. In light of the specific information feedback, the Operation Management Department shall designate related departments or personnel to answer via network or telephone within one week. The answers are to be put on record with regular collations and classifications; the common problems extracted from the records are to be incorporated into the Section of Common Q&A in the website, thus the constant enrichment of this Section shall facilitate the Applicants' inquiries and information sharing, thereby improving the communication efficiency and quality.

(B) Telephone Q&A:

1. To accept the Applicants' telephone inquiries, CDE opened a hotline (010-68537257) manned during 9:00-11:30 am, and 1:30-4:30 pm in weekdays, with automated voice prompts during the rest of the time.

2. To ensure the quality of telephone Q&A, the call will be recorded; after the call, you will be prompted to evaluate the quality of service.

3. While accepting the Applicants' telephone inquiries, relevant CDE staff shall work under the "First Inquiry Accountability System" to provide explicit and accurate answers to the inquired issues; evasions and perfunctory answers are not allowed; the inquired issues that cannot be accurately replied while answering the phone are to be recorded and promptly answered to the Applicants after the correct reply is obtained.

4. The Applicants should refrain from making telephone inquiries for the following information:

   (1) The progress information for the review of related varieties;

   (2) Major or critical information for decision-making in the technical review process;

   (3) Information that may involve the technical secrets of the Applicants;

   (4) Other information that should not be disclosed.

5. Relevant CDE management and review personnel shall answer for the Applicants' telephone inquiries during 3:00-4:30 pm on each working day.

6. The Applicants should evaluate the quality of telephone Q&A service, and propose reasonable suggestion, so that CDE can continuously improve the work level and service quality.

Article 23 CDE Q&A refers to the inquiries made by the CDE to the Applicants. In the process of variety management or drug review, when verifications or communications are to be made with the registration Applicants, relevant CDE management or review personnel can make CDE inquiries on the basic information of the applied project, and non-significant decision making information involved in the production process, quality standards, or instructions, etc.

Article 24 Relevant CDE staff can only raise inquiries on varieties within their respective

3.药审中心统一对申请人提交的“信息反馈”进行管理。具体由业务管理部负责根据信息反馈的具体内容，指定相应部门或人员在一周内予以网络或电话回复。对回复内容要求记录在案，并定期负责整理、归类；从中提炼出共性问题，经相应程序审核后，反馈纳入网站共性问题解答栏目，以此不断丰富网站共性问题解答栏目内容，便于申请人查询分享，从而提高沟通效率和质量。

（二）电话问询方式：

1.药审中心设电话专线（010-68537257），接受申请人电话问询，保证工作日上午9:00–11:30，下午1:30–4:30有专人接听，其他时间有自动语音提示。

2. 为保证电话问询质量，通话过程将被录音；通话结束后，将提示对服务质量进行评价。

3. 药审中心相关人员，在接受申请人电话问询时，要做到“首问负责”，负责针对问询事宜进行清晰、准确的答复；做到不推脱，不敷衍；对于接听电话当时，尚不能予以准确回复的问询内容，负责做好电话记录，并负责求得相关回复内容后，及时回复申请人。

4. 申请人不应针对以下信息进行电话问询：

（1）相关品种的审评进度、审评信息；

（2）技术审评过程中重大或关键的决策信息；

（3）可能涉及申请人技术秘密的信息；

（4）其他不宜披露的信息。

5. 药审中心相关管理人员和审评人员，于每个工作日下午3:00–4:30，接受申请人电话问询。

6. 申请人应对电话问询服务的质量作出评价，提出合理化建议，以便药审中心不断改进工作，提高服务质量。

二十三、中心问询是指药审中心向申请人提出的问询。药审中心相关管理或审评岗位人员，在品种管理或审评过程中，就申请项目基本信息，生产工艺、质量标准或说明书等资料中涉及的非重大决策信息，需要与注册申请人进行核实或沟通时，可采用中心问询方式。

二十四、药审中心相关人员，仅可针对自己负责审评的品种，向该品种申请人提出问询。

二十五、中心问询建议采用以网络系统（申请人之窗）为主，电话为辅的方式，向申请人提出询问。药审中心人员在提出问询之前，应首先告知申请人自己的姓名，审评部门，负责工作，问询内容，

review responsibilities to the corresponding Applicants.

Article 25 CDE Q&A is recommended to give priority to network system (Applicants' Window), which is supplemented by telephone inquiries to the Applicants. Before proposing an inquiry, CDE staff should first inform the Applicants of his/her own name, the affiliation of review department, duties, contents and purposes of the inquiry etc.

1. After proposing an inquiry, the relevant CDE staff should pay close attention to the Applicants' Reply, if necessary, they can call the applicants to confirm that the inquiries are received, and to remind the Applicants to give timely feedback; related inquiries and replies should be reflected in the review report of the corresponding varieties, to ensure the completeness of the evidence information for technical review.
2. If CDE inquiries are made by telephone, the related personnel should also timely make phone call records in the network system, and reflect the relevant situation in the technical review report, to ensure the completeness of the evidence information for technical review.

Article 26 The Applicants has the right and obligation to verify the "identity" of the inquiring CDE staff, when in doubt, they can refuse Q & A-Based Communication; for the convenience of relevant review issues of the applied varieties, it is advisable for the Applicants to adopt the other communication methods, such as the Applicants Q & A pattern, to communicate after confirming the other party is indeed the CDE review staff.

Chapter V Open-Day Communication

Article 27 Open-Day Communication refers to the vis-a-vis communication between CDE and the Applicants through prescribed patterns such as the Consultation Day and Open Day activities.

Article 28 The Open-Day is an activity organized by CDE to invite on regular basis the public, the media and the Applicants, through online appointment and registration, to visit CDE and exchange information. The Open Day activity is one of the effective ways to enhance the publicity, openness and transparency of technical review, and one of the platforms to promote CDE's popularity and communication with the public.

Article 29 CDE accepts the inquiries of the Applicants and answers their related questions on every Wednesday of working days during 8: 45 - 12:00 am, and 1:30-4:30 pm, in the CDE Consultation Hall. Since the inquiries in the Consultation Day are extemporaneous Q & A without appointment, its advisory quality and efficiency is nowhere near the other consultation patterns mentioned in this Practice, therefore it is not encouraged by CDE. After the implementation of this Practice for some time, CDE will organize the assessments of the demand for relevant communication, to gradually reduce the Consultation-Day hours, and continuously improve the quality and efficiency of other communication patterns.

Chapter VI Supplementary Provisions

Article 30 CDE Human Resources & Information Department, in conjunction with the Research & Evaluation Department and the Operation Management Department, shall perform quantitative evaluation on the contents involved in this Practice, and conduct regular examination and assessment on the communication with the Applicants, so as to continuously improve and enhance the Service Consciousness of the CDE staff, thereby improving their quality of service.

Article 31 All CDE staff shall abide by and implement this Practice.

Article 32 This Practice shall come into force as of the date of promulgation.

(July 26, 2012)

问询目的等内容。

1. 药审中心相关人员提出问询后，应关注申请人回复情况，必要时可通过电话确认对方是否收到问询，并提醒申请人及时反馈；相关问询和回复内容应体现在相应品种的审评报告中，以保证技术审评佐证资料的完整性。

2. 中心问询如通过电话方式提出，相关人员也应在网络系统中及时做好往来电话通话记录，并将相关情况体现在技术审评报告中，以保证技术审评佐证资料的完整性。

二十六、申请人有权利、有责任对提出问询的中心人员"身份"进行核实，当存疑虑时，可拒绝与其以问询式沟通交流方式进行交流；为不影响您申请品种的相关审评事宜，申请人可采取其他沟通交流方式，如申请人问询方式，在确认对方确为中心审评人员后，再行沟通交流事宜。

第五章 开放式沟通交流

二十七、开放式沟通交流系指药审中心和申请人之间通过咨询日、开放日等规定形式组织进行面对面交流的沟通方式。

二十八、开放日是药审中心通过网上预约报名的方式，定期邀请公众、媒体和申请人来中心参观、并进行交流的一项活动。开放日活动是增加技术审评工作的公开、开放、透明的有效途径之一，是药审中心加强对外宣传、沟通交流的平台之一。

二十九、药审中心于工作日的每周三上午8:45-12:00，下午1:30-4:30，在药审中心咨询大厅，接受申请人的咨询，负责解答申请人提出的相关问题。因咨询日的咨询是未经预约的即问即答式咨询，所以其咨询质量与效率远不如本规范所述的其他咨询方式，属于药审中心不予鼓励采取的咨询方式。我中心将于本规范实施一段时间后，组织评估相应沟通交流的需求情况，逐步减少咨询日咨询时间，并不断提高其他沟通交流的质量与效率。

第六章 附则

三十、药审中心人力资源与信息部应会同研究与评价部、业务管理部对本规范涉及内容进行量化考核，应定期对与申请人的沟通交流情况进行考核评估，以不断改进提高我中心人员的服务意识，从而提高服务质量。

三十一、药审中心各岗位人员均应执行本规范。

三十二、本规范自发布之日起执行。

（2012年7月16日）

The recruitment demand of pharmaceutical industry rose by 100% in the first half of 2012

In May 2012, the executive meeting of the State Council discussed and adopted the “12th Five-Year Development Plan for National Strategic Emerging Industries". With this favorable national policy, the pharmaceutical enterprises have accelerated the pace of development of new drugs and new medical devices, and this has stimulated the growing demand for talents in the pharmaceutical industry.

The latest data of healthr.com shows that, the recruitment demand of the pharmaceutical industry in the first two quarters of 2012 was up 100.5 percent, or doubled over a year earlier. A total of eight categories of jobs: Licensed pharmacists / drugstore Pharmacists, (TCM and Western medicine), product design engineers, nurses / nursing staff, Investment Managers / Specialists, quality management, biopharmaceutical / gene / purified protein, medical device sales, sales managers / representatives have become popular jobs in demand in the first half of 2012.

1. Licensed pharmacists / drugstore Pharmacists (WM), licensed pharmacist / Drugstore Pharmacists (TCM)

The recruitment demands for licensed pharmacist / Drugstore Pharmacists (WM), licensed pharmacist / Drugstore Pharmacists (TCM) increased by 261.90% (WM), 241.67% (TCM) respectively over the last year, and topped the list of demand growth, under the guidance of related national drug policies, pharmacist positions have become a popular first choice with huge space and fast speed for growth.

2. Product design engineer

The recruitment demand for product design engineers witnessed an increase of 215.9% over the same period last year, among the biggest gainers. In the "12th Five-Year" Plan period, the state strongly advocates independent R&D and innovative design; therefore product design engineers are highly sought after with rising market potential.

3. Nurses / nursing staff

The recruitment demand for Nurses / nursing staff rose by 156.8% over the same period last year, with the arrival of an aging society, the demand for nurses / nursing staff increases significantly.

4. Investment managers / Specialists

The demand for Investment Manager / Specialist recruitment saw an increase of 125.3% from a year earlier, and the high growth rate will continue.

5. Quality management personnel

The recruitment demand for Quality management talents saw an increase of 118.40% from a year earlier, with the state’s reinforced regulation of drug quality control, the growth of demand for quality management talents is very obvious.

6. Biopharmaceutical / gene

The recruitment demand for Biopharmaceutical / gene talents had an increase of 107.4%, with intensive introduction of relevant policies such as biopharmaceutical "Five-Year Plan" and the strong support of the state, the demand for biopharmaceutical / genetic talents will be greatly increased.

7. Medical device sales

The recruitment demand for medical device sales talents had a growth of 100.30% from a year earlier. During the "12th Five-Year Plan" period, many medical device manufacturers endeavor to seek breakthrough in high-end products

2012上半年医药行业招聘需求同比上涨100%

2012年5月，国务院常务会议讨论并通过了《〝十二五〞国家战略性新兴产业发展规划》。在国家政策利好下，医药企业加快了开发新药、新医疗装备的步伐，进而带动医药行业人才需求的不断增长。

医药英才网最新数据显示，今年前两季度医药行业的招聘需求较去年同期上涨了100.5%，涨幅翻番。执业药师/驻店药师（中医、西医）、产品设计工程师、护士/护理人员、招商经理/专员、质量管理、生物制药/基因/蛋白纯化、医疗器械销售、销售经理/代表共八大类职位成为上半年需求热门职位。

一、执业药师/驻店药师（西医）、执业药师/驻店药师（中医）

执业药师/驻店药师（西医）、执业药师/驻店药师（中医）招聘需求较去年同期分别增长261.90%（西医）、241.67%（中医）。需求涨幅位居榜首，在国家相关药品政策的导引下，药师类职位成为热门首选，人才需求增长空间大，增长速度快。

二、产品设计工程师

产品设计工程师的招聘需求较去年同期增长215.9%，涨幅居前。〝十二五〞期间，国家极力倡导自主研发，创新设计，使得产品设计工程师十分抢手，市场上升潜力大。

三、护士/护理人员

护士/护理人员的招聘需求较去年同期增长156.8%，随着社会老龄化的到来，护士/护理人员需求增幅明显。

四、招商经理/专员

招商经理/专员的招聘需求较去年同期增长125.3%，将持续较高的增长速度。

五、质量管理

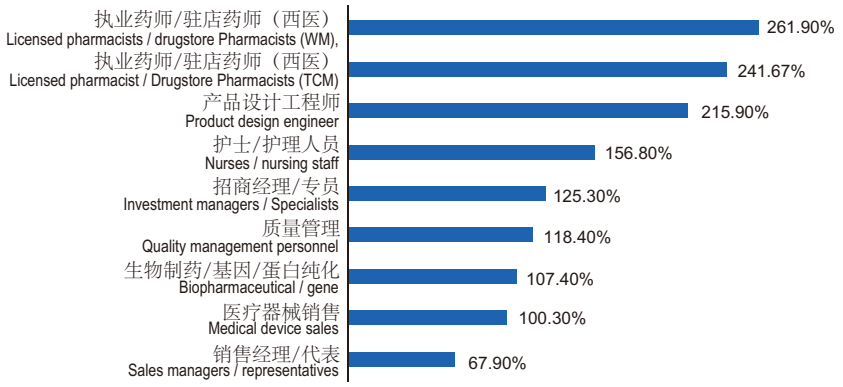
质量管理人才的招聘需求较去年同期增长118.40%，随着国家对药品质量的监管

so that domestic hospitals can become less dependent on imports. The sales of the medical device industry saw a fast expansion, so did the demand for sales persons.

8. Sales managers / representatives

The recruitment demand for sales managers / representatives saw an increase of 67.9% compared to last year, and recent pharmaceutical recruitment fairs have shown that pharmaceutical sales personnel are still hot jobs for major companies with stable growth in the demand for qualified personnel.

2012年上半年医药行业八大热门职位需求
Demands for 8 hot jobs of pharmaceutical industry in the first half of 2012



(July 18, 2012)

把控力度加强，质量管理人才需求增长十分明显。

六、生物制药/基因

生物制药/基因人才的招聘需求同比增长107.4%，随着生物制药“十二五”规划等相应政策的密集出台和国家的大力扶持，生物制药/基因人才需求将大幅度增长。

七、医疗器械销售

医疗器械销售人才的招聘需求较去年同期增长100.30%。在“十二五”期间，很多医疗器械生产企业表示要争取在高端产品上取得突破，以期改善本土医院依赖进口的状况。医疗器械行业销售加速扩张，医疗器械销售人才需求也随之上扬。

八、销售经理/代表

销售经理/代表与去年同期相比增长67.9%，从近期医药招聘会的情况看，医药销售仍是各大企业热招的职位，人才需求稳定增长。

（2012年7月18日）

Provided by Servier (Tianjin) Pharmaceutical Co., Ltd.
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Special column

The Assessment Results of “The 15th China Pharmaceutical Association - Servier Prize for Young Investigators in Medicinal Chemistry” Announced

In the morning of June 6, 2012, the 15th China Pharmaceutical Association --- Servier Prize for Young Investigators in Medicinal Chemistry Review Meeting was held in Beijing, Academician Zhang Lihe chaired the meeting. The judges carefully reviewed the recommendations and ratings of 18 candidates, and after consultation and democratic vote, the name list of proposed award-winning candidates was reported to the French Servier Research Institute. Five winners, including XIONG Bing from Shanghai Institute of Material Medical of Chinese Academy of Sciences and Zhu Yongqiang from Nanjing Medical University, were determined as awardees after the final assessment by French Servier Research Institute.

Co-founded by French Servier Research Institute and Chinese Pharmaceutical Association, “CPA-Servier Prize for Young Investigators in Medicinal Chemistry” dated back to 1997, in 15 years, it has encouraged outstanding young investigators in China to conduct new drug research with positive contributions.

(July 5, 2012)

特约专栏

第15届中国药学会——施维雅青年药物化学奖评审结果

2012年6月6日上午，第15届中国药学会---施维雅青年药物化学奖评审会议在北京召开，张礼和院士主持会议。各位评委对18名候选人的推评资料进行了认真审阅、评议以及民主投票后，推评出拟获奖人员名单上报法国施维雅研究院。最后确认中国科学院上海药物研究所的熊兵、南京医科大学药学院的朱永强等五人为第15届中国药学会-施维雅青年药物化学奖获得者。

“中国药学会－施维雅青年药物化学奖”始于1997年，法国施维雅研究院与中国药学会共同创立的，十五年来，为鼓励中国优秀青年开展新药研究工作做出了积极贡献。

（2012年7月5日）

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

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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