

## Quality management and supervision

### Most Recent Development on Good Supply Practice for Pharmaceutical Products

Good Supplying Practices are the basic standards of the operation, management and quality control of drug distribution enterprises. The new Good Supplying Practices (published as Order No. 90 by the Ministry of Health, the “**Revised GSP**”) which was promulgated on January 22, 2013, will take effect as of June 1, 2013, and will supersede the current Good Supplying Practices adopted by the State Food and Drug Administration (“**SFDA**”) on April 30, 2000. Compared to the current standards, the Revised GSP contains more administrative provisions, which will substantially help strengthen the criteria of quality control and the thresholds of market entry.

#### I. Framework of Revised GSP

The Revised GSP was issued with a definite target of “fully promoting one administrative method, strengthening two key links and resolving three tough issues”. “One administrative method” refers to the implementation of computer information management system for enterprises; “two key links” refers to drug purchase-sales channels and temperature and humidity control for warehouses; and “three tough issues” refers to voucher management, cold chain management and drug transportation.

The Revised GSP comprises of four chapters, namely the General Provisions, Quality Control for Drug Wholesale, Quality Control for Drug Retail, and Supplementary Provisions, totaling 187 articles.

#### II. Scope of Application of Revised GSP

The Revised GSP applies to drug distribution enterprises (including wholesalers and retailers). And as provided for in the Revised GSP, “any drug manufacturing enterprises selling drugs, or engaging in storage or transportation of drugs during the circulation process shall also observe the relevant requirements hereof”. The Revised GSP does not apply to (a) the pharmacies in medical institutions and family planning service providers in terms of the quality control of drug purchase, storage and maintenance, and (b) online drug sales in terms of quality control, the relevant regulations will be formulated by the SFDA separately.

#### III. Major Revisions Made

##### ● Enhanced Criteria and Requirements on Software and Hardware of Drug Distribution Enterprises

In respect of software, enterprises are required to establish a quality management system. The Revised GSP sets forth the detailed requirements for the establishment of department of quality management or the provision of personnel in charge of quality management and the documentation related thereto, and

enhances the qualification criteria for the personnel in the positions of person in charge of the enterprise, person in charge of product quality, person in charge of the quality management department, and staff working for departments of quality management, inspection and acceptance and maintenance.

In respect of hardware, enterprises are required to adopt the computer informationized management with a focus on the functional requirements of the facility, network environment, database and application software used in the computer management; enterprises are further required to use automatic temperature and humidity monitor for drug warehouses in order to conduct consistent and effective real-time monitoring on the environment therein, and are equipped with certain equipments or facilities for storage and transportation of refrigerated or frozen drug.

##### ● Certain New Rectification Mechanism Adopted

With respect to such issues as the non-standardized drug distribution activities, unclear purchase and sales channels, and disordered voucher management, the Revised GSP explicitly requires that the sales and purchase transactions be furnished with sales invoices, drug delivered from storage and in transit be accompanied by the list of goods which is to be checked upon delivery, and the vouchers, accounts and goods shall conform to each other during the logistic activities.

Enterprises are required to check and review if entrusted carriers have the transportation capacity and relevant quality assurance capability, enter into an agreement containing liabilities for breach of contract, and track by recording the quality of goods during the transportation.

The Revised GSP particularly strengthens the requirements on the equipments and facilities for storage and transportation of cold chain drug, with a special requirements on the handover processes, temperature monitor as well as trace and inspection for the transportation, goods receiving, and other links for the cold chain medicine, and put forward higher standard for the quality assurance capability of high-risk varieties.

The Revised GSP further requires drug distribution enterprises establish a system for enforcing the electronic monitoring for drugs, contains specific requirements as to such operations as code scanning and data uploading during the process of inspection and stock-in, stock-out, and sales of drugs and as to that the legal representative or person in charge of the drug retailers be professional pharmacists. Each drug retailer is required to engage

licensed pharmacist according to relevant state regulations, who shall be in charge of review and verifying prescriptions and providing guidance for rational drug use.

#### **IV. Formulation and Implementation of Relevant Supporting Documents**

The Revised GSP mainly provides for the basic guidelines for the drug distribution management and quality control, with the specific rules on the technical, professional and operation requirements during the drug distribution management process, such as computer systems, temperature and humidity monitoring system for warehouses, acceptance and inspection for drugs, storage and

transportation for refrigerated and frozen drugs, among others, will be formulated by SFDA as appendices to the Revised GSP for implementation.

#### **V. Three-year Transition Period**

SFDA sets forth a three-year transition period for the implementation of the Revised GSP. By such deadline in 2016, any enterprises failing to meet the criteria as provided in the Revised GSP will be ordered to cease its drug distribution operations. The detailed implementation guidelines are to be promulgated by SFDA.

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## 质量管理监督法律热点问题

### 新修订的《药品经营质量管理规范》

药品经营质量管理规范是企业药品经营管理和质量控制的基本准则。新修订《药品经营质量管理规范》(卫生部令第90号)(以下简称“药品GSP”)于2013年1月22日公布,自2013年6月1日起施行,届时将取代2000年4月30日以国家药品监督管理局局令第20号公布的现行《药品经营质量管理规范》。与现行规范相比,新修订药品GSP增加了许多新的管理内容,对企业经营质量管理要求和市场准入门槛明显提高。

#### 一、新修订药品GSP思路和结构

新修订药品GSP明确了“全面推进一项管理手段、强化两个重点环节、突破三个难点问题”的目标。一项管理手段就是实施企业计算机管理信息系统,两个重点环节就是药品购销渠道和仓储温湿度控制,三个难点就是票据管理、冷链管理和药品运输。修订后的药品GSP共4章,包括总则、药品批发的质量管理、药品零售的质量管理、附则,共计187条。

#### 二、新修订的GSP的适用范围

新修订的GSP适用于药品经营企业(包括批发和零售)和药品生产企业的销售药品、涉药物流等相关活动。但新修订的GSP尚不适用于医疗机构药房和计划生育服务机构的药品采购、储存、养护等质量管理规范以及互联网销售药品的质量管理。国家食品药品监督管理局将另行制定相关规定。

#### 三、修订的主要内容

##### 1. 新修订GSP全面提升了企业经营的软硬件标准和要求

在软件方面,新修订GSP明确要求企业建立质量管理体系,对设立质量管理部门或配备质量管理人员以及质量管理体系文件提出详细要求,并提高了企业负责人、质量负责人、质量管理部门负责人以及质管、验收、养护等岗位人员的资质要求。

在硬件方面,新修订GSP全面推行计算机信息化管理,着重规定计算机管理的设施、网络环境、数据库及应用软件功能要求;明确规定企业应对药品仓库采用温湿度自动监测系统,对仓储环境实施持续、有效的实时监测;对储存、运输冷藏、冷冻药品要求配备特定的设施设备。

##### 2. 针对薄弱环节增设一系列新制度

针对药品经营行为不规范、购销渠道不清、票据管理混乱等问题,新修订GSP明确要求药品购销过程必须开具发票,出库运输药品必须有随货同行单并在收货环节查验,物流活动要做到票、账、货相符,以达到规范药品经营行为,维护药品市场秩序的目的。

针对委托第三方运输,新修订GSP要求委托方应考察承运方的运输能力和相关质量保证条件,签订明确质量责任的委托协议,并要求通过记录实现运输过程的质量追踪。

针对冷链管理,新修订GSP提高了对冷链药品储存、运输设施设备的要求,特别规定了冷链药品运输、收货等环节的交接程序和温度监测、跟踪和查验要求,对高风险品种的质量保障能力提出了更高的要求。

新修订GSP规定了药品经营企业应制定执行药品电子监管的制度,对药品验收入库、出库、销售等环节的扫码和数据上传等操作提出具体要求,并规定了药品零售企业的法定代表人或企业负责人应当具备执业药师资格,企业应当按国家有关规定配备执业药师,负责处方审核,指导合理用药。

#### 四、相关配套文件的制定和施行

新修订GSP主要规定药品经营管理和质量控制的基本准则,就药品经营质量管理过程中的一些技术性、专业性或者操作性要求(如计算机系统、仓储温湿度监测系统、药品收货和验收、冷藏和冷冻药品的储存、运输等),有待国家食品药品监督管理局将制定相应细化的管理文件,以GSP附录的形式另行发布实施。

#### 五、过渡期的要求

国家食品药品监督管理局为新修订药品GSP实施设置了3年过渡期。到2016年规定期限后,对仍不能达到新修订药品GSP要求的企业,将依据《药品管理法》的有关规定停止其药品经营活动。具体实施步骤还有待国家食品药品监督管理局另行公告。

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