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Briefing note
October 2011

Greater China Healthcare and Life Sciences Bulletin: Autumn 2011

Welcome to the Autumn edition of our Greater China Healthcare and Life Sciences (HCLS) bulletin.

In this edition, we focus on off-label drug use and promotion, and provide a comparative analysis of China's legal regime with other jurisdictions in Europe and the US. Off-label drug use is a common practice in China and elsewhere and it remains a thorny issue for governments to regulate. In the US, much of the discretion to prescribe is left in the hands of the physician. In the EU, the Member States tend to adopt a similar approach with emphasis placed on the right of a patient to give informed consent to the off-label prescription of drugs. China takes the more restrictive approach of prohibiting both the off-label prescription and promotion of drugs, although enforcement has been inconsistent. It is our understanding that China's regulators are likely to review this area of law in the coming years and look to develop a more comprehensive and nuanced approach to the off-label use of drugs. In the meantime, international pharmaceutical companies should ensure their compliance programs in mainland China take account of the more restrictive nature of Chinese laws when engaging in promotional activities here.

In addition to our lead article, we have included two further legal updates on Good Manufacturing Practice (GMP) for pharmaceutical products and the Good Supply Practice (GSP) standards.

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A Comparative Review of Off-Label Pharmaceutical Use and Promotion in Europe, the US and China

In general terms, the phrase 'off-label' when applied to the use of drugs refers to the application of a pharmaceutical product outside the scope of use approved by the applicable drug administration authorities.[1] Off-label variances in that scope often pertain to its indication, patient group, dosage and duration of treatment.

The primary reason for off-label use is to address a deficit in effective approved drugs. This occurs mainly due to the lag in the discovery and development of effective drugs and their approval for authorised use by the relevant drug authorities. Further, if a drug is discovered to be effective in treating a second indication, obtaining the approval to treat that indication 'on-label' often involves a second regulatory pathway that that can be both lengthy and costly.

How widespread is the practice?

Europe

Studies published in the past 10 years have shown that off-label use in the European Union (EU) of drugs is widespread, in particular in pediatrics, oncology, neurology, infectology and geriatrics. For example, up to 90% of treatment for infants in hospital intensive care units is understood to be off-label.

Further, the costs of drugs prescribed off-label are often reimbursed by public health insurance companies.

United States

As in Europe, off-label prescriptions are reported to be significant, higher than 50% in some cases or some classes of patients. It is common practice for pharmaceutical companies to assess whether a drug that has been approved as safe and effective might also be suitable for new indications or applications. Indeed, such use can lead to new approved indications and uses. Economist Alexander Tabarrok showed that the rate of off-label prescription in the US is so high that most hospital patients receive at least one drug off-label.[2] Perhaps the most telling indicator of off-label prevalence is the tremendous amount of resources dedicated by both federal and state agencies, regulators and prosecutors in policing off-label use, coupled with the head-line making successes in prosecuting off-label cases. Investigation of off-label promotions of drugs remains a leading legal basis for pharmaceutical prosecutions in the US.

China

While effectively prohibited, off-label drug use is much more widespread in China than the law allows. Only a very limited number of surveys are known to have

Key issues

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1 In Europe, the equivalent of the drug label and insert sheet is the summary of the product characteristics (SmPC).

2 Assessing the FDA via the Anomaly of Off-label Drug Prescribing, The Independent Review: A Journal of Political Economy, Volume 5 Number 1 Summer 2000, http://www.independent.org/pdf/tir/tir_05_1_tabarrok.pdf

been conducted to ascertain activity levels. Of those that have, two surveys undertaken in pediatric hospital wards in Beijing and Suzhou respectively show off-label use of up to 22% of all medicines prescribed.[3]

Sources of regulation – in what circumstances is it permitted?

Europe

Despite off-label pharmaceutical use being common practice, there is very little regulation on an EU-wide basis. For example, there is no legal definition of off-label use at EU level.

However, promoting the prescription of a pharmaceutical product for a purpose that has not been authorised is expressly prohibited.[4]

Whether or not physicians are allowed to prescribe pharmaceuticals on an off-label basis depends on the laws of the Member States. For example, in Germany, physicians are permitted to apply pharmaceuticals on an off-label basis. In some cases they are even required to apply pharmaceuticals off-label in order to avoid malpractice claims by patients.

Prior to any off-label treatment, physicians must comprehensively inform patients of the risks associated with use of the drug, including that it lacks a marketing authorization for the intended use and that the risks associated with the treatment are unknown and possible difficulties may arise in connection with the reimbursement of the treatment costs by health insurance companies. Provision of insufficient information on any of these matters can entitle patients to bring damages claims.

US

US laws and regulations do not directly regulate the prescription of medicines by physicians. Instead, physicians are expected to use their medical judgment, acting in the best interests of the patient, in prescribing medications. Provided a physician is well informed about the product, and has a credible clinical justification, they may prescribe any drug product approved by the US Food and Drug Administration (FDA), including for off-label uses.

Drug manufacturers, on the other hand, are prohibited from marketing or promoting off-label uses of their products to induce commercial sales. The legal basis derives from legislation prohibiting the "misbranding" of drugs. After the FDA approves the product as safe and effective for a specified use or indication, any promotion by the manufacturer for other uses which are not specified in an FDA-approved label renders the product misbranded.

Off-label cases are typically prosecuted under the False Claims Act, which prohibits the filing of false claims for payment to the federal government. Liability can arise if a pharmaceutical company causes false claims to be submitted to government healthcare programs by promoting uses that are not medically accepted indications, and therefore not covered by those programs.

The legal framework does not prohibit the exchange or dissemination of truthful and non-misleading information about a product's unapproved uses in specific circumstances. In 2009, the FDA promulgated guidance on "good reprint practices" for distribution of scientific publications on off-label uses.[5] The guidance does not address all potentially permissible ways companies can convey information within the bounds of the law. Moreover, tension remains in the law between the government's goal of regulating off-label promotion and a company's constitutional right to free speech afforded by the first amendment. Some companies have successfully argued that their activities of disseminating truthful, non-misleading information about off-label uses is constitutionally permitted free speech.

China

The legal system in China places a positive obligation on physicians to only prescribe drugs in accordance with their approved use. By law, the approved drug label and insert sheet 'guides' the appropriate use of the drug.[6] Further, physicians must prescribe drugs "in accordance with" the drug label and insert sheet.[7] Whether either of these terms prevents minor deviations from the drug label and insert sheet is not clear. If found to have violated these provisions, physicians will be at risk of a formal warning, suspension of their practice certificate for between six months to one year, or even the withdrawal of their practice certificate. Comparable rules also apply to pharmacists.

There have however been circumstances in which off-label use in China has been permitted. One such circumstance occurred during the SARS outbreak in 2004 when certain forms of antibiotic were permitted, even encouraged, by authorities to be prescribed in excess of their permitted dosages specified on the approved product label and insert sheet. In March 2010, 20 senior chief pharmacists from 17 hospitals in Guangdong province issued a statement on off-label prescriptions. Many of the recommendations in the statement are similar to the principles already adopted in some EU countries, but tend to be

[3] ZHANG, Wei,门诊超药品说明书用药的调查分析(Survey and Analysis of Outpatient Drug Use that Goes Beyond the Scope of Package Inserts), 中国医院用药评价与分析2010年02期, Evaluation and Analysis of Drug-Use in Hospitals of China, 2nd Issue (2010) and WANG, Hai-ying, 北京大学第三医院儿科门诊超说明书用药调查与分析 (Analysis of Outpatient Off-label Use in the Third Hospital of Peking University) 中国医院用药评价与分析2011年02期, Evaluation and Analysis of Drug-Use in Hospitals of China, 2nd (2011).

[4] Article 87, Directive 2001/83/EC.

[5] http://www.fda.gov/oc/op/goodreprint.html

[6] Article 9, Provisions on the Administration Drug Labels and Insert Sheets (《药品说明书和标签管理规定》).

[7] Article 14, Measures on Administration of Prescriptions (《处方管理办法》).

more specific than the requirements in the US. [8]

Responsibility for enforcement and potential consequences for non-compliance

Europe

Manufacturers who are found to have illegally promoted off-label use of their drugs face serious consequences in the EU with such consequences dependent on the national laws of the EU Member States. In Germany, the healthcare supervisory authorities might render administrative fines of up to EUR 50,000 per case. However, the authorities have rarely been active and even more rarely rendered an administrative fine.

In saying that, there has been extensive litigation in the EU between pharmaceutical manufacturers illegally promoting off-label use on the one hand and their competitors, or consumer and fair trade protection organizations on the other hand. At present, the associated risks for drug manufacturers are comparatively low and do not normally exceed more than a small fraction of the costs of a given marketing campaign.

Product liability is considered a more relevant area of concern for pharmaceutical manufacturers illegally promoting off-label use. EU product liability law operates a strict liability regime i.e. pharmaceutical manufacturer are liable even without fault. The crucial question in connection with product liability and off-label use is whether the off-label use could reasonably be expected. The instructions for use, the summary of product characteristics (SmPCs), labelling, advertisements and other information provided by a pharmaceutical manufacturer are important resources in that context. Moreover, even tolerating an off-label use can lead to a drug manufacturer incurring liability under relevant product liability laws.

US

Off-label cases are vigorously prosecuted in the US. Pharmaceutical companies have in numerous cases over the past decade paid fines and fees to settle criminal and civil cases of tens or hundreds of millions of dollars, and in some recent notable cases, more than a billion dollars. Cases are brought by numerous parties, most commonly the US Department of Justice, the Office of Inspector General of the US Department of Health and Human Services, the Attorney Generals of the individual states, and the fraud control units of multiple federal and state agencies. The FDA has been particularly active, launching a healthcare fraud prevention initiative called HEAT in May 2009, as well as the Bad Ad outreach program with the goal of encouraging health care professionals (HCPs) to recognize and report suspected untruthful or misleading drug promotion in May 2010.

These activities have together generated many billions of dollars in fines and settlements in recent years. The government has been successful in encouraging the participation of private individuals (e.g., current or former employees, competitors, HCPs) as whistle-blowers in so-called "qui tam" actions, where whistle-blowers are entitled to a percentage of the recovery of the penalty as a reward for exposing the off label usage. In these cases, the whistle-blower is entitled to receive significant payments, frequently millions of dollars.

Prosecutors have in some cases sought to impose individual accountability by pursuing criminal cases against the executives involved. In addition to facing prison sentences, individual executives and managers may be targeted under provisions which lead to their exclusion from participating in federal health care programs or debarment from regulatory activities before the FDA, effectively preventing them from working in the industry.

China

As described above, the "off-label" prescription of drugs is not permitted in China. Under the current Chinese regulatory regime however, the promotion of drugs off-label is not directly addressed and a formal legal sanction or remedy where a civil claim arises does not fit easily under current pharmaceutical regulatory, product liability, criminal or tort law. Advertising drugs off-label is more clearly prohibited, and any advertisement of a drug must conform to its State Food and Drug Administration approved product label and insert sheet.[9]

Conclusion

Markedly different approaches to the regulation of off-label drug use and promotion exist in the world's largest pharmaceutical markets. Despite the commonplace nature of off-label use, the legal regime on an EU-wide basis remains underdeveloped compared with that of many of the EU's Member States where the concept of informed consent is prevalent. While the United States permits both off-label use and now, in certain circumstances, its promotion, this issue remains contentious and commonly litigated as pharmaceutical companies and the court systems adapt to an evolving regulatory regime. Notwithstanding the potential benefits of regulating and supervising off-label drug use, China has yet to introduce a permissive regulatory regime. There are signs, however, that the Chinese authorities are reviewing the existing regime with a view to introducing a more comprehensive and nuanced approached in the future.

[8] Zheng and Xu, The Journal of Managed Care Pharmacy, October 2010 http://www.amcp.org/data/jmcp/640.pdf

[9] Article 61, Drug Administration Law (《药品管理法》), Article 6 of the Standards for Drugs Advertisement Censorship and Publishing (《药品广告审查发布标准》).

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Latest Edition of GMP Management Measures for Pharmaceutical Products Released

On 17 January 2011, the Ministry of Health promulgated the Good Manufacturing Practice for Pharmaceutical Products (2010 version) (2010 GMP)[1] , which raised the threshold for the first time since 1999 for drug manufacturers to qualify for Good Manufacturing Practice (GMP) certification.[2]

As the government body charged with supervising and enforcing the standards set out in the 2010 GMP, the State Food and Drug Administration (SFDA) released the Management Measures for Good Manufacturing Practices (GMP) Certification for Pharmaceutical Products with effect from 2 August 2011 (2011 GMP Management Measures)[3]. The 2011 GMP Management Measures supersede the Management Measures for GMP Certification for Pharmaceutical Products issued on 7 September 2005 (2005 GMP Certification Measures)[4] .

A summary of the key differences between the 2011 GMP Management Measures and the 2005 GMP Management Measures is set out below:

- A new concept of the "Risk Assessment Principle" has been introduced. The SFDA now has the ability to consider both the nature and seriousness of the defects that it identifies in GMP certificate applicants, the type of pharmaceutical products appraised, and the effectiveness of rectification measures the applicant has taken, before determining whether or not to grant GMP certification. This principle allows the SFDA more discretion during the GMP certification process.

- Expanded provisions for suspension/ revocation of the GMP certification. The 2011 GMP Management Measures provide that GMP certificates shall be suspended where: (a) workshop requirements fail to comply with GMP standards; (b) a manufacturer is ordered to cease operation and rectify its non compliance with other pharmaceutical related laws; and (c) any other circumstance which in the opinion of the SFDA or its competent branch requires a suspension of the GMP certificate.

- Specific timeline for GMP certification process. The 2011 GMP Management Measures provide a more detailed timeline/procedure for each step of the GMP certification process, including in respect of technical examinations, on-site inspections and final determinations.

Key issues

New rules for managing GMP certification released

New supervision and enforcement powers

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1 药品生产质量管理规范(2010年版)

2 Good Manufacturing Practice for Pharmaceutical Products (1998 version), in Chinese药品生产质量管理规范（1998版）promulgated in this instance by the SFDA on 18 June 1999

3 药品生产质量管理规范认证管理办法（2011年）

4 药品生产质量管理规范认证管理办法（2005年）

- Quality management system for the drug certification authorities. For the first time, the local drug certification authorities will be subject to a quality management system with the central level SFDA responsible for evaluating the local systems which are put in place.

- Follow-up inspection. Each holder of a GMP certificate will be subject to at least one interim inspection by the SFDA under the 2011 GMP Management Measures during the GMP certificate's 5-year effective period.

Earlier this month the SFDA announced that eight recently constructed Chinese wholly domestic owned drug manufacturing operators were the first to be certified pursuant to the 2011 GMP Management Measures.[5] In line with government plans to ensure the consolidation of a sector consisting of around 5,000 domestic pharmaceutical manufacturers, 90% of which are small to medium sized enterprises, it is expected that the supervision and enforcement powers set out in the 2011 GMP Management Measures will be put to regular use to secure the transition of existing manufacturer operations to the standards set by the 2010 GMP.[6]

[5] http://www.sda.gov.cn/WS01/CL0088/65396.html

[6] The transition period established by the Notice of Implementing the Good Manufacturing Practice for Pharmaceutical Products (2010 version) (in Chinese 要求做好药品生产质量管理规范（2010年修订）贯彻实施工作的通知) to meet the 2010 GMP standards is: (i) 31 December 2013 for existing drug manufacturers producing blood products, vaccines, injections and other sterile pharmaceutical products; and (b) 31 December 2015 for manufacturers of other pharmaceutical products.

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Amended Good Supply Practice (GSP) Standards Set to Impact Pharmaceutical Distribution Sector

On 1 August 2011, the State Food and Drug Administration (SFDA) issued a notice seeking public comments on the Amended Good Supply Practices for Pharmaceutical Products (Draft for Comments) (Draft GSP Standards) (in Chinese 药品经营质量管理规范(征求意见稿)). Below we set out the key features of the Draft GSP Standards and consider their potential impact on the pharmaceutical distribution industry in China.

1. Introduction of New Standards

Once implemented, the Draft GSP Standards will replace the Good Supply Practices for Pharmaceutical Products issued on 30 April 2000 (in Chinese 药品经营质量管理规范). The Draft GSP Standards propose a more comprehensive and onerous set of compliance standards on pharmaceutical distributors.

The following are some of the key features of the Draft GSP Standards:

- Information management systems. For the first time, drug wholesalers are required to establish comprehensive and well-maintained information systems, covering the entire distribution chain from purchase to the ultimate sale of the products

- Cold chain management, including requirements on temperature control and monitoring and observation equipment during drug product transportation

- After-sales services requirements including procedures on handling complaints by customers and the recall and withdrawal of drug products

- Record and documentation management requirements, particularly in respect of records obtained during the purchase of drugs by pharmaceutical distributors from other suppliers

- Higher standards in respect of staff, particularly key management personnel

- Regular inspection of equipment including temperature/humidity monitoring devices, and cold storage transportation

- Detailed requirements on transportation management, including transportation vehicle standards

Industry commentators expect that the Draft GSP Standards will include a transition period for operators similar to that provided for in the Administrative Measures for Good Manufacturing Practices Certification for Pharmaceutical Products (in Chinese 药品生产质量管理规范认证管理办法)), though details have not yet been made available.

2. Industry Impact

The transfer of responsibility for supervision of the drug distribution regime from the SFDA to the Ministry of

[1] Outline of the Plans for the Development of the Pharmaceutical Distribution Sector from 2011 to 2015 (in Chinese 全国药品流通行业发展规划纲要 (2011-2015)). For further details, see our client briefing: MOFCOM: Consolidating China's pharmaceutical distribution sector (July 2011)

Key issues

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Commerce (MOFCOM") in 2009 acted to accelerate the concentration of the industry. In May 2011, the MOFCOM set out the policy outline for the sector for the next five years (Outline).[1] According to the Outline, the MOFCOM aims to cultivate one to three large nationwide pharmaceutical groups by the end of 2015, each with annual sales of over RMB100 billion; and 20 regional pharmaceutical companies with annual sales level of over RMB10 billion. Compared with the US pharmaceutical distribution sector, market concentration in the Chinese pharmaceutical market is very low. In 2009, the aggregate revenue of the three largest distributors, namely Sinopharm, Shanghai Pharma and Jointown Pharmaceutical, accounted only for 20.9% of the total pharmaceutical distribution market, whereas the three largest US distributors (i.e. AmerisourceBergen, McKesson and Cardinal Health) accounted for 97% of the US distribution market during the same period.

It is no secret that the PRC central government is seeking to encourage consolidation in the pharmaceutical distribution sector. Raising GSP standards is an effective way to ensure that some of the smaller operators are incentivised to merge into larger companies that possess the capital necessary to bring operations in line with the more stringent industry standards.

3. Conclusion

Sector consolidation is already well underway with major drug distribution companies having already embarked on an aggressive strategy of acquiring small to medium-sized drug distribution operators. The release of the Draft GSP Standards and their ultimate promulgation provides further impetus to this strategy.

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Greater China Healthcare and Life Sciences Bulletin

Selected regulatory changes July – September 2011

State Food and Drug Administration (SFDA)

二〇一一年七月十一日 – 国家食品药品监督管理局关于征求《保健食品召回管理办法（征求意见稿）》意见的通知（食药监稽函[2011]191号）（于2011年8月10日前，以纸质及电子邮件形式反馈）

"SFDA Notice on Soliciting Public Opinions Regarding the "Administrative Measures on the Recall of Health Products (Consultation Draft)", issued on 11 July 2011.

Deadline for submission : 10 August 2011.

二〇一一年七月二十一日 – 国家食品药品监督管理局关于规范保健食品有关行政许可事项的通知 （国食药监保化[2011]321号 ）（自2011年9月1日起施行）

"SFDA Notice on Regulating the Administrative Licensing Matters Relating to Health Products", promulgated on 21 July 2011 and effective as of 1 September 2011.

二〇一一年八月二日 – 国家食品药品监督管理局关于印发《药品生产质量管理规范认证管理办法的通知》（国食药监安[2011]365号）（自发布之日起施行）

"SFDA Notice on Issuing the Administrative Measures for the Recognition of the Good Manufacturing Practice (GMP) for Pharmaceutical Products " , promulgated on 2 August 2011 and effective as of the same date.

二〇一一年八月二日 – 国家食品药品监督管理局关于印发《药品生产质量管理规范检查员聘任及考评暂行规定的通知（国食药监安[2011]366号）（自发布之日起施行）

"SFDA Notice on Issuing Interim Provisions for Regulating the Examination and Employment of Examiners of the Goods Manufacturing Practice (GMP) for Pharmaceutical Products ", promulgated on 2 August 2011 and effective as of the same date.

二〇一一年八月二日 – 国家食品药品监督管理局关于治伤软膏等48种药品转换为非处方药的通知（国食药监注[2011]350号）

"SFDA Notice on Changing 48 Kinds of Drugs (Including Injury Healing Ointments) into Non-prescription Drugs", promulgated on 2 August 2011.

二〇一一年九月十六日 – 国家食品药品监督管理局关于印发医疗器械不良事件监测工作指南（试行）的通知（国食药监械[2011]425号）

"SFDA Notice on Issuing a Working Guide on the Supervision of Malfunctioning Medical Devices (Trial Implementation)", promulgated on 16 September 2011.

二〇一一年九月二十二日– 关于认可国家食品药品监督管理局天津医疗器械质量监督检验中心心脏除颤器等医疗器械产品和项目检测资格的通知(国食药监械[2011]429号)

"SFDA Notice on the Accreditation of Testing Qualifications for Cardiac Defibrillators by the Tianjin Medical Devices Supervision & Testing Center and other Medical Devices", promulgated on 22 September 2011.

二〇一一年九月二十三日 – 国家食品药品监督管理局关于停止生产销售使用盐酸克仑特罗片剂的通知（国食药监办[2011]432号）

"SFDA Notice on Banning the Manufacture and Sale of Clenbuterol Hydrochloride Tablets", promulgated on 23 September 2011.

The General Office of the SFDA

二〇一一年八月二十日 – 国家食品药品监督管理局办公室关于启用新版本药品GMP证书的通知（食药监办安[2011] 137号） （于本通知发布之日起正式启用）

"Notice of the General Office of the SFDA on the Use of the New Version of Pharmaceutical Products GMP Certificate", promulgated on 20 August 2011 and effective as of the same date.

Department of Drug Safety & Inspection of the SFDA

二〇一一年八月一日 – 国家食品药品监督管理局药品安全监管司关于征求《药品经营质量管理规范》(征求意见稿)修改意见的通知 （食药监安函 [2011]106号）（于2011年8月31日前将修改意见反馈）

"Notice of the Department of Food Safety Supervision of the SFDA on Soliciting Public Opinions Regarding the ' Administration of the Good Supply Practice (GSP) for Pharmaceutical Products (Consultation Draft)' ", issued on 1 August 2011.

Deadline for submission : 31 August 2011.

Department of Health Food & Cosmetics Hygiene Supervision of the SFDA

二〇一一年八月一日 – 国家食品药品监督管理局保健食品化妆品监管司关于征求《保健食品功能范围调整方案(征求意见稿)》意见的函 (食药监保化函[2011]322号) (于2011年8月31日前将意见反馈)

"Letter of the Department of Health Food & Cosmetics Hygiene Supervision of the SFDA on Soliciting Public Opinions Regarding the 'Proposal for Adjusting the Functional Coverage of Health Products (Consultation Draft)'", issued on 1 August 2011.

Deadline for submission : 31 August 2011.

二〇一一年八月二日 – 国家食品药品监督管理局保健食品化妆品监管司关于征求修订《辅助降血糖功能评价方法 (征求意见稿)》等意见的函 (食药监保化函[2011]325号) (修改意见于2011年8月31日前反馈)

"Letter of Department of Health Food & Cosmetics Hygiene Supervision of the SFDA for Soliciting Public Opinions on Amending the 'Methods for Evaluating the Auxiliary Function of Blood Sugar Reduction (Consultation Draft)' ", issued on 2 August 2011.

Deadline for submission : 31 August 2011.

Department of Policies, Laws and Regulations of the SFDA

二〇一一年九月二十六日 – 国家食品药品监督管理局政策法规司关于《食品药品安全责任约谈办法 (征求意见稿)》公开征求意见的函 (食药监法函[2011]63号) (于2011年10月25日前将修改意见反馈)

"Department of Policies, laws and Regulations under SFDA is Soliciting Public Opinions on the 'Measures for Food and Drug Safety Responsibility (Consultation Draft)'", promulgated on 26 September 2011.

Deadline for submission : 25 October 2011.

State Council

二〇一一年七月一日 – 国务院关于建立全科医生制度的指导意见 (国发[2011] 23号)

"Guiding Opinions of the State Council on Establishing General Practitioner System", promulgated on 1 July 2011.

二〇一一年九月十七日 – 国务院关于印发中国老龄事业发展“十二五”规划的通知 (国发[2011] 28号)

"Notice of the State Council on Issuing the 12th Five Year Plan for the Development of China's Undertakings for the Aged", promulgated on 17 September 2011.

The General Office of the State Council

二〇一一年七月二日 – 国务院办公厅关于进一步加强乡村医生队伍建设的指导意见 (国办发[2011]31号)

"Guiding Opinions of the General Office of the State Council on Further Strengthening the Construction of the Rural Doctor Team", promulgated on 2 July 2011.

二〇一一年七月五日 – 国务院办公厅转发发展改革委财政部卫生部关于清理化解基层医疗卫生机构债务意见的通知 (国办发[2011]32号)

"Notice of the General Office of the State Council on Forwarding the Opinions of NDRC, MOF and MOH Concerning the Settlement of and Resolution of Issues Relating to the Debts of Basic Medical Healthcare Institutions", forwarded on 5 July 2011.

The Legislative Affairs Office of the State Council

二〇一一年七月二十日 –国务院法制办公室关于公布《农药管理条例 (征求意见稿)》公开征求意见的通知 (在2011年8月31日前提出意见)

"Notice of the Legislative Affairs Office of the State Council on Soliciting Public Opinions Regarding the " Administrative Regulations on Agricultural Pesticide (Consultation Draft)", issued on 20 July 2011.

Deadline for submission : 31 August 2011.

Ministry of Health (MOH)

二〇一一年七月二十日 – 卫生部关于印发《卫生监督信息报告管理规定 (2011年修订版)》的通知 (卫监督发[2011]63号) (自发布之日起施行)

"MOH Notice on the Administrative Provisions on the Reporting of Information on Hygienic Supervision (2011 Amended Version)", promulgated on 20 July 2011 and effective as of the same date.

二〇一一年八月 – 卫生部发布《中国妇幼卫生事业发展报告 (2011)》

August 2011 - Report on Women and Children's Health Development in China (2011) (Q&A in Chinese - 《中国妇幼卫生事业发展报告 (2011)》问答)

二〇一一年八月三日 – 卫生部关于公开征求《抗菌药物临床应用管理办法 (征求意见稿)》意见的通知 (意见收集截止日期为：2011年9月5日)

"MOH Notice on Soliciting Public Opinions Regarding the 'Administrative Measures for the Clinical Applications of Anti-infective Medicines' ", issued on 3 August 2011.

Deadline for submission : 5 September 2011.

二〇一一年九月七日 – 卫生部、发展改革委、财政部关于印发《全国鼠疫防治“十二五”规划（2011-2015年）》的通知（卫应急发[2011] 72号）

"The 12th Five Year Plan for Countrywide Plague Control and Prevention (2011-2015)", jointly promulgated by MOH, NDRC and MOF on 7 September 2011. The General Office of the MOH

二〇一一年九月二日 – 卫生部办公厅关于征求《疾病分类与代码（修订稿）》意见的函 （卫办综函[2011] 830号）（意见收集截止日期为：2011年9月30日）

"Letter of the General Office of the MOH on Soliciting Public Opinions Regarding the Classification and Code of Diseases (Amended Draft)", promulgated on 2 September 2011.

Deadline for submission : 30 September 2011.

National Development and Reform Commission (NDRC)

二〇一一年八月四日 – 国家发展改革委关于调整激素、调节内分泌类和神经系统类等药品价格及有关问题的通知 （发改价格[2011]1670号）

"NDRC Notice on Price Adjustment and Relevant Issues Regarding Drugs Related to Hormone, Endocrine, Nervous System and others", promulgated on 4 August 2011.

二〇一一年八月二十九日 – 国家发展改革委、科技部印发关于加快推进民营企业研发机构建设的实施意见的通知

"Notice on Implementation of the Opinions on Accelerating the Construction of Research and Development Institutions of Private Enterprises', jointly promulgated on 29 August 2011.

The National People's Congress of the PRC (NPC)

二〇一一年七月四日 – 全国人民代表大会常务委员会《职业病防治法修正案（草案）条文及草案说明》 意见征集截止日期：2011年7月31日

"NPC is Soliciting Public Opinions on Explanations on Draft Amendments to Laws on Prevention and Control of Occupational Diseases", issued on 4 July 2011.

Deadline for submission : 31 July 2011.

Ministry of Human Resources and Social Security (MOHRSS)

二〇一一年七月四日– 关于领取失业保险金人员参加职工基本医疗保险有关问题的通知（人社部发[2011]77号）

"MOHRSS Notice on Relevant Issues Concerning the Participation in the Basic Medical Insurance by Employees Who are Receiving Unemployment Insurance Funds", promulgated on 4 July 2011.
Ministry of Environmental Protection (MOEP)

二〇一一年六月二十四日 – 关于发布国家环境保护标准《企业环境报告书编制导则》的公告第51号 （HJ 617-2011）（自2011年10月1日施行）

"Announcement No. 51 of MOEP on Issuing the Standards of National Environmental Protection – 'Guidelines for Preparation of Corporate Environmental Reports (HJ 617-2011)' ", promulgated on 24 June 2011 and effective as of 1 October 2011.

Ministry of Agriculture (MOA) , Ministry of Industry and Information Technology (MIIT), Ministry of Environmental Protection (MOEP), State Administration for Industry and Commerce (SAIC) and General Administration of Quality Supervision, Inspection and Quarantine (GAQSIQ) ("Five authorities")

二〇一一年六月十五日 – 农业部、工业和信息化部、环境保护部 、国家工商行政管理总局、 国家质量监督检验检疫总局五部门发布进一步禁限用高毒农药管理措施的公告第1586号

"Announcement No. 1586 - Administrative Measures on Further Banning the Use of High-toxic Pesticides", jointly promulgated by the Five authorities on 15 June 2011.

Ministry of Science and Technology (MOST)

二〇一一年六月二十四日 – 科学技术部令第15号 《高等级病原微生物实验室建设审查办法》（自2011年8月1日起施行）

MOST Order No. 15 - "Measures for Examining the Establishment of a High Grade Micro-organism Laboratory", promulgated on 24 June 2011 and effective as of 1 August 2011.

Shanghai Food and Drug Administration

二〇一一年七月二十五日 – 上海市食品药品监督管理局关于对第一类医疗器械生产企业登记信息现场核查的指导意见 （沪食药监械注 [2011] 568号）

"Guiding Opinion of Shanghai Food and Drug Administration on On-the-Spot Inspection on Registration Information of Type I Medical Device Production Enterprises", promulgated on 25 July 2011.

二〇一一年八月二日 –上海市食品药品监督管理局关于进一步规范医用氧经营质量管理的通知 （沪食药监流通[2011] 585号）

"Notice of the Shanghai Food and Drug Administration on Further Regulating the Quality Management of Operations Relating to Medical-Use Oxygen", promulgated on 2 August 2011.

二〇一一年八月十二日 – 上海市食品药品监督管理局关于上海市创建国家药品安全示范县（区）工作的实施意见 （沪食药监流通[2011] 620号）

"Opinions on the Implementation of the Creation and Establishment of Model Counties (Regions) for National Drug Safety in Shanghai", promulgated by Shanghai Food and Drug Administration on 12 August 2011.

二〇一一年八月二十三日 –上海市食品药品监督管理局关于加强上海市药品生产企业接受境外制药厂商委托加工药品监督管理的通知 （沪食药监药安[2011] 658号）

"Notice of Shanghai Food and Drug Administration on Strengthening the Administration and Supervision of Drug Manufacturing Enterprises which Accept the Entrustment by Overseas Drugs Manufacturers for the Processing of Drugs in Shanghai", promulgated on 23 August 2011.

二〇一一年八月二十四日 –上海市食品药品监督管理局关于市级医药商品储备仓储管理事项的复函（沪食药监流通[2011]663号）

"Reply Letter from Shanghai Food and Drug Administration on the Issues Regarding the Administration of Warehouse Reserves of Drug Commodities at City Levels", Issued on 24 August 2011.

二〇一一年九月六日 – 上海市食品药品监督管理局关于推进本市药品生产经营企业贯彻落实《药品不良反应报告和监测管理办法》的通知（沪食药监药安[2011]700号）

"Notice of Shanghai Food and Drug Administration on Enhancing Shanghai Drug Manufacturing Enterprises to Thoroughly Implement the Administrative Measures on the Report and Monitoring of「Adverse Drug Reactions", promulgated on 6 September 2011.

Shanghai Municipal Health Bureau

二〇一一年七月一日 – 上海市卫生局关于下发《上海市优质医院创建工作实施方案》的通知（沪卫医管[2011]16号）

"Notice of the Shanghai Municipal Health Bureau on Issuing the 'Proposal for Implementation of Work Establishing High Quality Hospitals in Shanghai Municipality' ", issued on 1 July 2011.「

二〇一一年七月十二日 – 上海市卫生局、上海市物价局关于进一步规范本市营利性医疗机构医疗服务和价格行为的通知（沪卫规财[2011] 25号）（自下发之日起施行）

"SMHB and SPB Joint Notice on Further Regulating the Medical Services and Price Behavior of Profit-making Medical Institutions in Shanghai", jointly promulgated on 12 July 2011 and effective as of the same date.

二〇一一年七月二十八日 – 上海市卫生局、上海市质量技术监督局关于印发《关于加强医疗卫生领域标准化试点项目管理的若干意见》的通知（沪卫法规 [2011] 014号）

"Several Opinions on Strengthening the Administration of Pilot Project for Standardization in the Medical and Hygienic Sectors", jointly promulgated by SMHB and SMBQTS on 28 July 2011.

二〇一一年八月二日 – 上海市卫生局关于重申加强医师执业注册管理工作的通知（沪卫医政[2011] 076号）

"SMHB Notice on Strengthening the Administrative Work for the Registration of Practicing Doctors", promulgated on 2 August 2011.

二〇一一年八月十二日 – 上海市卫生局关于开展上海市家庭医生临床能力培训的通知（沪卫基层[2011] 012号）

"SMHB Notice on Commencement of Training of Clinical Working Ability for Family Doctors in Shanghai", promulgated on 12 August 2011.

二〇一一年八月二十四日 – 上海市卫生局关于开展上海市新农合定点医疗机构检查的通知（沪卫基层[2011] 013号）

"SMHB Notice on Commencement of the Inspection of Fixed New Rural Cooperative Medical Care Institutions in Shanghai", promulgated on 24 August 2011.

二〇一一年八月三十一日 – 上海市卫生局关于加强本市西医学习中医人员执业行为管理的通知（沪卫中医[2011] 041号）（自发布之日起施行，有效期五年）

"SMHB Notice on Strengthening the Administration of Traditional Chinese Medicine Practitioners' Behavior in Learning Western Medicine in Shanghai", promulgated on 31 August 2011 and effective as of the same date for five years.

二〇一一年九月十三日 – 上海市卫生局关于转发《卫生部关于印发<卫生监督信息报告管理规定（2011年修订版）>的通知》的通知 （ 沪卫监督[2011] 027号）

"SMHB Notice on Forwarding 'MOH Notice on the Administrative Provisions on the Reporting of Hygiene Supervision Information (2011 Amended Version)' ", promulgated on 13 September 2011.

Shanghai Development and Reform Commission (Price Bureau)

二〇一一年七月二十九日 – 上海市发展和改革委员会(物价局) 关于发布《上海市药品价格管理办法 (试行)》的通知 （沪发改价费[2011] 007号）（自二〇一一年九月一日起施行）

"Notice of the Shanghai Development and Reform Commission (Price Bureau) on the Administrative Measures on Prices of Drugs in Shanghai (Trial Implementation)", promulgated on 29 July 2011 and effective as of 1 September 2011.

二〇一一年七月二十九日 –上海市发展和改革委员会(物价局) 关于发布《上海市医疗机构药品集中招标采购价格管理办法 (试行)》的通知 （沪发改价费[2011] 008号）（2011年9月1日起正式实施）

"Notice of the Shanghai Development and Reform Commission (Price Bureau) on the Administrative Measures for Drug Concentration Price Bidding Procurement of Medical Institutions in Shanghai (Trial Implementation)", promulgated on 29 July 2011 and effective as of 1 September 2011.

二〇一一年八月十九日 – 上海市物价局、上海市卫生局、上海市医疗保险办公室关于调整在本市销售的部分激素、调节内分泌类和神经系统类药品最高零售价格的通知 （沪价费 [2011]013号）（自2011年9月1日起执行）

"Notice on Adjustment of the Highest Retail Prices of Drugs Related to Certain Hormone, Endocrine and Nervous System Sold in Shanghai", jointly promulgated by SPB, SMHB and SMMI on 19 August 2011 and effective as of 1 September 2011.

China Healthcare Group

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Ann practises intellectual property law with an emphasis on global patent strategy. She counsels biotechnology, pharmaceutical and other life sciences clients, helping them obtain, protect and enforce their IP rights in China and abroad. Ann is familiar with many technical areas including molecular biology, cancer therapeutics, vaccines, gene therapy, transgenic plants and animals, nutritional supplements, herbal extracts, drug formulation and delivery, diagnostic kits, and medical devices. She is admitted in New York and the US Patent and Trademark Office.

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