



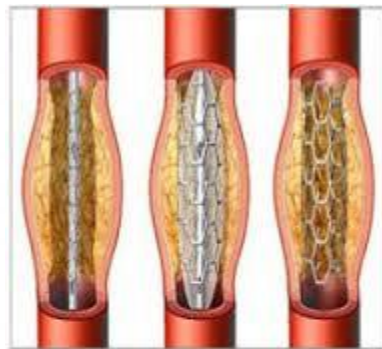
Photo credits: ©UL TRA.F/Gettyimages

Latest challenges in Pharmaceutical Industry 新形势下的制药行业假冒挑战



Victor Shao SANOFI China Product Security Head
邵克亮 赛诺菲中国产品安全负责人
Haikou 2019.11.22

Cure or Kill?治病还是致命？



支架进入 支架扩张 支架留在冠脉内



Real Scene of Fake Medicine manufacturing 假药生产真实场景



Content/内容

1 Pharmaceutical industrial Counterfeiting features

一、制药行业制售假特征

2 Pharmaceutical ACF influences by New Drug Act amendment

二、药品管理法的修改对打击假药的影响

3 Some thinking

三、一些思考

Pharmaceutical industrial Counterfeiting features 制药行业制售假特征

1 Criminal people feature 犯罪人员特点

Region: Northeast China; Anhui/Hebei

地域特性：东北籍(生产销售)、安徽河北（换药团伙）

Relationship: Familial; Close relatives; hidden;

关系特性：家族性、封闭性、隐蔽性

Behavior: Professional; false ID; Recidivism

行为特性：职业化（制造、销售）、伪造身份、累犯

Criminal Age: lower age

年龄特性：低龄化

Logistics employee deliberately involving fake drugs

快递物流领域的快递员有意识的参与假药运送



Geographical features 地理特点

Northeast, Beijing, Tianjin...

东北、北京、天津等

Cangnan (Zhejiang)

浙江苍南等地

Expand to Hebei, Henan, Shandong, Hubei...

拓展到河北、河南、山东、湖北等地

Manufacturing, Distributing to nationwide

制造组装后批发至全国

Northeast Drug Counterfeiters set up nationwide web

东北籍假药贩子全国流窜



Illegal Profits资金

Sudden huge profits

暴利

Example of Vicious Circle

恶性示范循环

False ID

使用虚假身份

Logistics Money Collection

物流代收货款



Physical features物理特性

Most fake Drugs contains no API for example Cardiovascular

药品大都无有效成分 如假冒心脑血管疾病用药

Focus on fast turnover, high volume & value medicine including CV, Diabetes, Oncology medicines

集中在用量大、周转快、价值高的品种如心脑血管、糖尿病、癌症用药

Fake Drugs(fully counterfeits + recycle genuine package of Drugs/Medical Devices) Change the date of Expired Drugs & MD

假药（全假冒+回收药品/医疗器械真品包装材料）回收过期药/器械+混合



Marketing features 推广特点

NO Professional Medical knowledge

没有专业的医药知识

Mostly leverage QQ/WeChat to wholesale & sell

主要通过QQ/微信批销

Deliver via Logistics(Like Deppon) by false ID

物流（如德邦）发货时使用虚假身份

Single way communication(instant add friends, delete after deal)

单线联系 随时添加好友 交易后立即彼此删除联系人

Minimize tracking investigation risk in whole process

最大限度的降低全环节被调查追踪的风险



How to handle 如何应对？

Replay key Counterfeiting & Wholesale

还原主要制假、批发环节

Leverage Big Data!运用大数据！



Machines & packaging for Counterfeiting 假药生产机器、包装材料



压板机 Blister machine



打码机 coding machine



Security label 防伪标

谁在买卖？ Who sell & buy?

查扣后是销毁还是拍卖 After seizure, destruction or auction?

One case 案例

From one box of fake drugs to whole counterfeiting medicine criminal gang 从药店销售一盒假药到追踪制售假网络

<http://hb.sina.com.cn/news/j/2016-01-13/detail-ifxnkkux1234895.shtml>

十堰破亿元网络制售假药大案 抓获犯罪嫌疑人189人

- 十堰市公安局与食药局组成联合调查组，循线层层追踪，深挖窝点，历时大半年，破获了这起特大网络制假售假案，于2015年6月捣毁假药生产窝点5个，销售窝点67个，在全国各地抓获犯罪嫌疑人189人。
- 该案先后被公安部、国家食药监局督办。现已查明，2013年7月至今，犯罪嫌疑人韩某、刘某等人，以天津西青区和南开区、北京房山区和丰台区、哈尔滨呼兰区和松北区为主要销售窝点，以亲友为纽带，通过QQ联络、物流收货、代收货款等网络隐秘方式，向山西、陕西、河南、黑龙江、内蒙古、河北等21个省70余个地市销售假冒心脑血管、糖尿病等100余种假药，涉案产值一亿余元。

Very decent cooperation with Alibaba Group!

与阿里巴巴集团的反假冒合作非常卓有成效！

Drug Act Amendment 药品管理法修订

- Effective from Dec. 1, 2019 2019年12月1日施行
- Cancel GMP/GSP certification 取消GMP/GSP认证
- Adopt Marketing Authorization Holder (MAH) System 采用上市许可持有人制度
- **Establish a sound drug traceability system 建立药品可靠追溯制度**
- Establish a pharmacovigilance system 建立不良反应监测机制
- Increase penalties for drug violations 增加药品违法惩罚力度



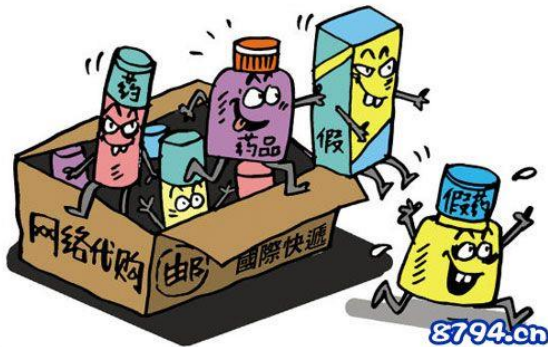
Online distribution of Drugs 在线销售药品

- Previous: **online** distribution of **prescription drugs** and drugs that has special control requirements is **prohibited**. 以前：禁止网售处方药及特殊管制药物
- NEW: stipulate vaccines, blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs shall not be sold online. 新：除了疫苗、血液制品、麻醉药品、精神类药物、医疗用毒性药品、放射性药品、药品类易制毒化学品等国家特殊管理的药品除外
- Comment: **Online prescription drugs selling would be opened with condition** by detailed regulation in the future. 网络销售处方药有条件放开，具体细则有望出台



Definition: counterfeit drugs 假药定义

- Article 98: Production (including dispensing), distribution and use of counterfeit drugs and inferior drugs are prohibited.
- Counterfeit drug has one of the following characteristics: 有下列情形之一的，为假药：
 - Its components are different from those prescribed by state pharmaceutical standards; 药品所含成份与国家药品标准规定的成份不符的；
 - A non-medical substance is passed off as a medicine, or one medicine is passed off as another; 以非药品冒充药品或以他种药品冒充此种药品的；
 - Where the medicine has deteriorated; 变质的；
 - Where the indications or the functions marked on the labels of the pharmaceuticals do not fall within the prescribed scope. 所标明的适应症或者功能主治超出规定范围的

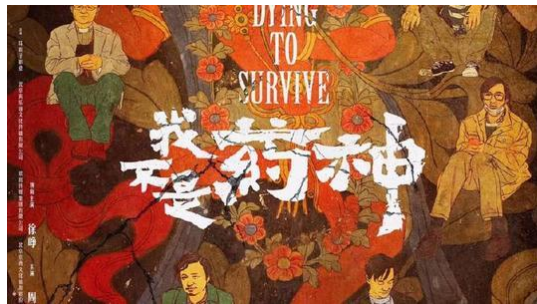


Definition: inferior drugs劣药定义

- Inferior drug has one of the following characteristics: 有下列情形之一的, 为劣药:
 - Its components do not conform in quantity to that required by State pharmaceutical standards; 药品成份的含量不符合国家药品标准的;
 - Where the medicine has been contaminated; 被污染的; (**used to be handled as counterfeit**)
 - Expiry date is not indicated or is altered; 未标明有效期或者更改有效期的;
 - Batch number is not indicated or is altered; 不注明或者**更改生产批号的**;
 - The medicine has passed its expiration date; **超过有效期的**;
 - The medicine has been added presumptuously with ~~color or preservative additives, spice, disguising odor or~~ supplementary materials; 擅自添加防腐剂、辅料的药品;
 - The medicine fails to meet the prescribed standards in other respects. 其他不符合药品标准规定的
- It is prohibited to produce or import products without obtaining drug approval documents. (**used to be handled as counterfeit**)

Import drugs without approval 未经批准进口药品

- Previous: The drug that is imported without approval, shall be handled as counterfeit drug.
- NEW: Article 124 **The import of drugs without approval shall be an administrative violation.** The unlawfully imported drugs and unlawful income shall be confiscated, and shall concurrently be fined a sum of money **more than fifteen less than thirty times** the value of the medicines unlawfully imported. If the value of the goods is less than RMB100,000, it shall be calculated as RMB100,000. **Where a small number of drugs that have been legally listed abroad are imported without approval, the minor circumstances may be mitigated or exempted from punishment according to law.** 未取得药品批准进口药品的，属于行政违法行为；没收违法进口药品和违法所得，并处违法进口药品货值金额十五倍以上三十倍以下的罚款；货值金额不足十万元的，按十万元计算。特别规定未经批准进口少量境外已合法上市的药品，情节较轻的可以依法减轻或者免于处罚。
- Comment: Import drug without approval is not handled as counterfeit drug. Small amount of imported drugs without approval may be considered as minor circumstances. Large amount of imported drugs without approval may involve illegal operation or smuggling.



Penalty Increased 处罚加重



- Production and distribution of counterfeit drugs:
- Article 110 Those who produce or sell counterfeit drugs shall have his unlawfully produced or sold drugs and any unlawful income confiscated, and be ordered to suspend production or business operations pending rectification, and be revoked of approval certificate of pharmaceuticals, and be held criminally responsible. Those who are not considered a crime by law, shall concurrently be fined a sum of money **more than fifteen less than thirty times (more than two but less than five times)** the value of the medicines unlawfully produced and sold. **If value of the goods is less than RMB100,000, a fine of not less than RMB 1.5 million but not more than RMB 3 million shall be imposed.** If the circumstances are serious, the party shall have Pharmaceutical Production License, or Pharmaceutical Trade License or Dispensing Permit of Medical Organizations revoked.
- 生产、销售假药的，没收违法生产、销售的药品和违法所得，责令停产、停业整顿，吊销药品批准证明文件，依法追究刑事责任；**依法不认为是犯罪的，并处违法生产、销售药品货值金额十五倍以上三十倍以下（二倍以上五倍以下）的罚款；货值不足十万元的，并处一百五十万元以上三百万元以下的罚款；情节严重的，吊销《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》。**

Penalty Increased处罚加重

- Production and distribution of inferior drugs:
- Article 111 Those who produce and sell inferior drugs shall have his unlawfully made and sold medicines and any unlawful income confiscated, and be concurrently fined the sum of money **more than ten but less than twenty times** ~~(more than two but less than three times)~~ the value of the medicines unlawfully made or sold. **If value of the goods is less than RMB100,000, a fine of not less than RMB 1 million but not more than RMB 2 million shall be imposed.** If the circumstances are serious, the party shall be ordered to suspend production or business pending rectification, or have the pharmaceutical approval certificate revoked and his Pharmaceutical Production License, or Pharmaceutical Trade License or Dispensing Permit of Medical Organizations revoked. Those whose acts constitute a crime will be investigated for criminal liabilities.
- 生产、销售劣药的，没收违法生产、销售的药品和违法所得，并处违法生产、销售药品货值金额**五倍以上二十倍以下**~~（一倍以上三倍以下）~~的罚款；**货值不足十万元的，并处一百万元以上二百万元以下的罚款；**情节严重的，责令停产、停业整顿或者撤销药品批准证明文件、吊销《药品生产许可证》、《药品经营许可证》或者《医疗机构制剂许可证》；构成犯罪的，依法追究刑事责任。

Punitive Damages 惩罚性赔偿

- Producing counterfeit or inferior drugs or selling them knowingly, thus causing serious damage to death or health, in addition to demanding compensation for losses, the victim's family members or close relatives may also demand corresponding punitive damages.
- 生产假药、劣药或明知是假药、劣药仍然销售，造成死亡或者健康严重损害的，受害者家属或者近亲属除要求赔偿损失外，还可以要求相应的惩罚性赔偿。
- Pay 10 times of medicine spending or 3 times of damages
- 支付价款十倍或者损失三倍的赔偿金

Some thinking 一些条文思考

- 62条 网络交易第三方平台提供者应按照国家药监局规定省级药监备案

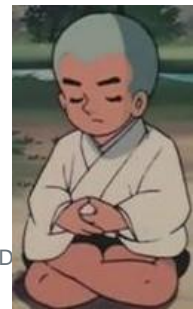
平台对许可持有人经营企业资质进行审核 保证符合法定要求 发现违法 及时报告告诉在地县级以上药监 立即停止网络交易平台服务

- 89 药品广告省级广告审查机关批准
- 115 未取得药品经营许可证的 没收违法所得处15-30倍罚款 不足10万的按照10万计算

Fake drug distributor(person) on WeChat & QQ selling fake RX medicine What is the legal responsibility of TenCent Company? Has TenCent also assume some supervision responsibility like positively monitor & forbidden RX medicine Selling, freeze account or report to local FDA or Police?

“假药”贩子（个人）在微信/QQ上销售(假冒)处方药 微信/QQ是否适用以上规则担责？

微信/QQ是否需要承担一定的监管责任（如主动监控并禁止发布处方药销售信息、封号、向所在地药监报告或公安部门分享情报线索？）



- ~~120 知道或者应当知道~~属于假药、劣药或者本法124条第一款至第五款规定的药品而为其提供储存、运输等便利条件的 没收全部储存、运输收入并处1-5倍罚款 情节严重的个处5-15倍罚款（最低按照5万元计算）
- 129 药品经营企业未从上市许可持有人或具有经营资格的企业购进药品的 责令改正 没收违法购进的药品和违法所得 并处违法购进药品货值2-10倍罚款 情节严重的处10-30倍罚款吊销许可证 金额不足5万的按5万元计算
- 131条 网络交易平台提供未履行资质审核、报告、停止提供网络交易平台服务等义务的 责令改正 没收违法所得 处20万-200万罚款 情节严重的停业整顿 处200-500万罚款
- Article 120 Offered convenient supports including storage, logistics etc. with awareness or should know fake drugs involvement, should be confiscated all related incomes and 1-5 times fines, if with serious situation would get 5-15 times fines(with bottle line as RMB 50K)
- Article 131 Online platform haven't accomplished certificates checking, report, stop offering online dealing service as platform legal responsibilities, should be commanded to execute corrective measures and confiscate all illegal incomes together with RMB 200K-2M Fine. If with serious conditions, should close business for correction with RMB 2M-5M fine.



Further Thinking 思考

WeChat/QQ has main feature as communication tool. When it was used as main tool for deadly damage to Patients safety/health by fake Cardiovascular, Diabetes and Oncology medicines (assume if leverage WeChat/QQ selling Drugs & weapons?)

微信、QQ有通信工具属性，通信自由VS危害患者生命健康的心脑血管、糖尿病、肿瘤假药（对比下如果通过沟通微信买卖毒品、凶器呢？）

Influential platforms including Alibaba, TenCent, JD and PDD etc. are independent but Counterfeiters maximize all platform conveniences. Can they corporate & align together in anti-counterfeiting?

Alibaba、腾讯、JD、PDD等平台各自为政，目前无法打通直接合作。制售假者恰恰各个平台都会最大化使用，社会共治能否从平台之间合作同步开展？

Fake medicines export to Other countries

假药出口到国外

Integrate Counterfeits manufacturing & Distributing big data? Currently leverage professional & reliable Police

整合制售假药犯罪团伙的大数据？高素质的专业公安执法队伍！





Victor
法国 巴黎

SANOFI 

Victor.shao@Sanofi.com
18019028139

