China's new blacklist: the impact for drug and device lawbreakers

Shaoyu Chen, *Scott Cunningham*, *Jason Ma*, *Eric Carlson* and *Yan Luo* explain how the blacklist will work.

On 1 October 2012, new rules will become effective in China under which the country's healthcare products regulators will establish and publicise blacklists of companies and individuals that have been found, through administrative or judicial proceedings, to have committed a serious violation of drug or device law[1].

Companies and individuals engaged in the research, development, manufacturing and distribution of drugs or devices in China need to be aware of the serious implications of the blacklists. They will have to comply diligently with the new rules in order to mitigate corporate or individual liability and business interruption.

The Rules on Administration of Blacklist for Drug Safety (Trial Implementation) were promulgated by the State Food and Drug Administration on 13 August, finalising an SFDA proposal that was published on 30 May[2]; although the title of the regulation does not include medical devices, the rules apply to device manufacturers and distributors as well. Under the rules, the SFDA and provincial food and drug administrations must each establish and publicise a blacklist of companies and individuals that have committed certain serious violations and they must update the blacklists periodically on their websites. The blacklist will contain the names and details of the violating companies and, in certain situations, those individuals who are direct managers or otherwise directly responsible for the violations (responsible individuals). Through this "naming and shaming" mechanism, the SFDA has indicated its intention to deter violations and increase enforcement activities against companies or individuals that have violated certain laws and regulations.

Who will be blacklisted?

Article 7 of the rules requires the regulators to blacklist companies involved in the following seven specified circumstances, where administrative penalties have also been imposed:

- producing or selling counterfeit or inferior drugs, where one of the following licences has been revoked: a drug marketing authorisation, pharmaceutical manufacturing licence, pharmaceutical distribution licence or a permit for pharmaceutical preparations by medical institutions;
- producing unregistered devices or devices that fail to meet national or industry standards (where the violation is serious); or producing or selling devices that violate other legal requirements and have caused serious safety consequences. In addition, in each case, one of the following licences must have been revoked: device registration certificate, device manufacturing licence or device distribution licence;
- concealing information or submitting false information during the process of applying for an administrative permit relating to drugs or devices;
- obtaining an administrative permit, approval or other qualification by providing false certificates, documents, data or samples, or through other improper methods, such as fraud or bribery;

> Because of the public nature of the blacklist, companies or individuals risk damage to their reputation and credibility

- during the investigation stage of an administrative enforcement action, falsifying or intentionally destroying relevant premises; transferring, hiding, falsifying or destroying pertinent evidence; refusing or avoiding investigation or refusing to provide information or data; or using (without authorisation) goods that have been detained;
- having been criminally penalised due to violations of drug or device laws and regulations; and
- producing or selling drugs or devices that caused serious harm due to deviations from legally required conditions or intentional/egregious violations of the drug or device laws and regulations.

With respect to individuals, Article 7 also requires that the blacklists include those "responsible individuals" who have been prohibited for 10 years from engaging in drug production or distribution activities due to: (a) producing or distributing counterfeit drugs; or (b) serious violations involving production or distribution of substandard drugs. This ten-year prohibition is provided by Article 76 of the Drug Administration Law (2001).

Interestingly, the rules also prohibit a drug manufacturer, for 10 years, from employing a responsible individual to engage in drug production or distribution activities if the individual was involved in any device law violation described in the second bullet of the above list. This 10-year prohibition is not provided by Article 76 of the Drug Administration Law or by Articles 35-38 of the Medical Device Supervision and Management Rules (2000). Articles 35-38 include penalties for similar device law violations including fines, revocation of licence and criminal sanctions. They do not include, however, any employment prohibition.

Penalties and prohibitions

Existing law specifies the penalties and prohibitions for certain violations. The new rules specify that the blacklists must include these penalties and the duration of any of the prohibitions that have been previously imposed, which are as follows:

- a rejection of an application for a marketing authorisation or other types of administrative permit and a one-year prohibition against applying for an administrative permit for a company or an individual that concealed relevant information or submitted false information in an application for such a permit. If the application is for a clinical trial, the prohibition is three years under existing drug laws and regulations;
- a revocation of any permit obtained – and a three-year prohibition against filing for the same type of permit – through false certificates or documents, fraud or bribery, except where the permit fraudulently obtained is a drug manufacturing or distribution permit, in which case the prohibition is currently five years under existing drug laws and regulations, and will retain the longer period.

How will the blacklist work?

The blacklist will function as follows:

- within 15 business days after the relevant administrative penalty becomes effective, the SFDA and/or the provincial food and drug administration will add the name of the penalised company and/or individual to the blacklist on the agency's website;
- for those penalised companies or individuals reported to the SFDA by a provincial food and drug administration, the SFDA must add the information to the blacklist on the SFDA website with five business days;
- the information posted will include the company name, business address – or individual name, title and partially redacted citizen national identification number – violation, administrative penalty decision and duration of the prohibition. The posting will stay online for the duration of the prohibition or for two years if no specific duration is set out under the laws and regulations; and
- after the expiration of the posting period, information on blacklisted companies and/or individuals will be moved to an archived database that will still be publicly accessible.

The implications of being blacklisted

Under the new rules, the SFDA and provincial food and drug administrations will be obliged to publicise certain administrative penalties, which otherwise would not necessarily be available to the public. Because of the public nature of the blacklist, companies or individuals risk damage to their reputation and credibility among consumers and the healthcare community.

The blacklist will be in addition to existing provincial blacklists required by the Ministry of Health. MOH notices from 2007 and 2010 require provincial departments of health to establish publicly available blacklists of companies engaging in commercial bribery during the purchase or sale of pharmaceutical products and bar such companies from public tenders for two years.

The new SFDA blacklist and pre-existing provincial department of health blacklists are parallel to, but somewhat different from, a recently centralised database of companies and individuals found guilty of certain bribery offences. This database is searchable by the public but only by making a request to China's Supreme People's Procuratorate.

References

1. *Rules on Administration of Blacklist for Drug Safety (Trial Implementation) (in Chinese), 13 August 2012, www.sfda.gov.c n/WS01/CL0844/74236.html*
2. *Chen S, Cunningham S, Ma J, Carlson E, Luo Y, China's 'naming and shaming' proposal and the ramifications for violators of drug and medical device laws, Scrip Regulatory Affairs, 25 July 2012*

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Pharma news in brief

Australia restricts use of cough and cold medicines in children

Drug sponsors marketing cough and cold medicines in Australia will have to start amending their labelling and packaging from 1 September onwards to state that such products should not be given to children below six years of age, the Therapeutic Goods Administration says. Labels will also have to reflect that for children aged six to 11 years, these medicines should only be allowed on the advice of a doctor, pharmacist or nurse practitioner.

EMA to explore how it will proactively publish drug trial data

The European Medicines Agency is to hold a public workshop on 22 November to discuss how best to move forward with its plan to proactively publish clinical trial data and give interested parties access to full data sets. There are a number of practical and policy issues that need to be addressed before complex data sets can be made available to a wider audience, the EMA says.

European Commission names companies in pay-for-delay probe

The European Commission has fired warning shots at Lundbeck and Servier in its long-running probe into the possibility that pharmaceutical companies have engaged in anti-competitive business practices. This is the first case that may lead to commission action against companies for "pay-for-delay" tactics to keep competing generics off the market.

Pharma pay-for-delay concerns up again in Europe

The number of patent settlement deals signed between originator pharma companies and generics manufacturers that may violate EU anti-competition rules tripled in 2011 over the previous year, according to the European Commission's third monitoring report.

India outlines essential elements of informed consent for drug trials

India's Central Drugs Standard Control Organization has laid out 14 "essential elements" that must be included in informed consent documents used to enrol subjects in a drug trial.

Malaysia updates drug registration guide

The Malaysian National Pharmaceutical Control Bureau (BPFK) has updated its guidance on registration of medicinal products to add information on, among other things, how a new drug product should be classified.

"More balanced" appeals might make NICE nicer, says UK pharma industry

The panel that hears appeals against guidance from NICE, the health technology appraisal body for England and Wales, will become more independent from the institute, according to England's Department of Health. The move gives companies the chance of more "balanced" hearings, says the Association of the British Pharmaceutical Industry.

UK ABPI updates guidelines on Phase I drug trials

The UK research-based pharmaceutical industry association, ABPI, has updated its guidance on conducting Phase I clinical trials to take into account regulatory changes in this area since the document was last updated in 2007.

US FDA invites public to nominate drugs for paediatric development

The US Food and Drug Administration has given the general public until 4 September to suggest the names of one or more adult-use drugs or biologics for which they believe paediatric formulations should be developed. Companies whose products are nominated by the public will be offered the opportunity to present a US paediatric study plan before a 4 December meeting of the FDA's paediatric subcommittee of the Oncologic Drugs Advisory Committee.

Pre-merger rules change in US

Many more licensing agreements among drug makers could come under US antitrust review – about 30 more transactions per year – if a newly proposed change in the reporting rules is adopted, which could mean added scrutiny, fees potentially up to $280,000, an additional waiting period to seal a deal and more paperwork for biopharma firms.

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