

QUALITY MATTERS

Alan Adcock discusses product quality in China and outlines China's bottom-up approach to IP awareness and protection.

In September 2008, China once again found itself at the centre of international media attention for all the wrong reasons. Reports circulated that four infants had died and more than 50,000 others had fallen ill after consuming dairy products that had been contaminated by melamine. Although initial reports focused on a single milk producer, it soon became clear that more than 20 companies were implicated in the scandal. The sight of thousands of anxious parents queuing for hours in hospitals, waiting for their children to be checked for kidney ailments, finally spurred Chinese officials into action. Health inspectors began testing thousands of batches of milk for traces of the chemical substance, while police detained individuals who had been identified as complicit in the contamination.

This is not, of course, the first time that the quality of goods produced by Chinese companies has come under the microscope. These recently unfolding events closely mirror earlier scandals involving the quality of Chinese products. In the summer of 2007, for instance, China's image as the world's factory for all things made fast, cheap and good came to a screeching halt. Spurred by the US media, revelations of countless examples of poor-quality, faulty and harmful products coming from China made the world stop and ask itself whether low prices were really worth the risk of potentially unsafe products. The number and types of shoddy products recalled that summer in the US alone were disturbing, especially those posing the most immediate risks, such as food and pharmaceuticals.

Investigations by the US media confirmed that with regard to food and drug imports, China is considered a regular source of products containing carcinogens, illegal pesticides and additives, as well as banned antibiotics and preservatives. The US Consumer Product Safety Commission has

reported that as much as 60 percent of recalled goods in the US are Chinese-made. The usual course of action most governments take is to return such products to their country of origin, but many times, the same goods will be reshipped or sent to countries with less onerous inspections.

Following the 2007 revelations, we saw some very positive outcomes from the otherwise tragic situation. Firstly, many new policies, regulations and procedures concerning pharmaceuticals that had been in the ministerial pipeline for years were fast-tracked and implemented. These included more transparent drug approval and registration procedures, pricing standards, advertising controls, retail/wholesale directions, and harsher criminal penalties for dealing in fake products.

Secondly, the Chinese consumer is now more aware of issues regarding product quality, which naturally has led to a greater understanding and appreciation of intellectual property rights. Poisoned products (often sold under counterfeit brands) affect the Chinese too. The melamine milk scandal provides another wake-up call, and shows that there are still lessons to be learned from 2004, when at least 50 infants died and another 200 or so were left severely malnourished after being fed unsafe and fake infant formula. On July 10, 2007, Zheng Xiaoyu, the former head of the State Food and Drug Administration (SFDA), was executed after antibiotics approved under his watch were responsible for the deaths of 10 people, before being recalled from the market. Zheng was found to have accepted over \$800,000 in bribes and gifts from various drug manufacturers in order to fast-track approval of the poisonous drugs. The court held that Zheng had failed in his duty to "make careful arrangements for the supervision of medicine production, which is of critical importance to people's lives".

SFDA shake-up

The SFDA was established in its current form in 2003. Before this, the regulation of food and pharmaceuticals was overseen by a host of ministries and respective agencies. Bringing this all together under one regulatory roof was intended to streamline procedures and bring China's system in line with those in other countries. What was not foreseen, however, was how consolidation might result in a concentration of approval authority in the hands of select ministers with little or no oversight in terms of how they carried out their duties. Zheng Xiaoyu's execution was seen as Beijing's shot across the SFDA bow to 'shape up'.

On the day of Zheng's execution, the *New Measures for the Administration of the Registration of Pharmaceuticals (New Measures)* were released by the SFDA and became effective on October 1, 2007 (the People's Republic of China's (PRC) National Day). The *New Measures*, which replace the earlier 2005 Measures, have significantly curtailed individual regulator authority over drug registration and approval, clinical trials, generic pharmaceutical approval, and manufacturing. While data protection safeguards remain in place in terms of new drug application dossiers, most of the SFDA's internal procedures and requirements, which previously were arbitrarily and sometimes inequitably disseminated and practised, are now to be made publicly available and mostly online. By separate measures, in 2007, SFDA officials were precluded from investing in pharmaceutical companies and, as of April 2007, were meant to have completely divested themselves of any interests they had held.

One of the cornerstones of China's current Eleventh Year Plan is technological innovation, and to

encourage this in the field of pharmaceuticals, the *New Measures* provide for a number of new procedures, such as definite timetables for the approval of new drugs; a revised definition of “new drugs”, which for the first time, specifically precludes mere reformulations of existing pharmaceutical products that have no improved qualities (such reformulations may now be submitted for generic approval); and a new fast-track approval procedure for certain specially emphasised medicine products, such as those used in the treatment of HIV/AIDS, rare diseases and terminal illnesses. The conduct of preclinical and clinical trials, especially in terms of on-site inspections and testing, has been expanded and now includes local FDA inspections of generic applicants and approved manufacturers. Increased inspections of pharmaceutical manufacturers were actually mandated by the SFDA back in 2004, when the Good Manufacturing Practice (GMP) certification was first required of all drug factories in China. With nearly 200,000 licensed drug manufacturers in China, most experts predict that a majority will fail these GMP certification inspections, which are meant to be completed this year.

Advertising controls

On March 3, 2007, the SFDA and the State Administration for Industry and Commerce jointly issued their *Provisions for Pharmaceutical Advertisement Standards (the Provisions)*. Drug advertisement and drug labelling has always been the responsibility of local (meaning either provincial or municipal) FDAs, but this joint national directive is intended to end differences in how drug products are marketed and labelled, through the use of countrywide standards. In addition to further establishing what type of information is required in adverts and labels, the *Provisions* also dictate prohibited content, such as unsubstantiated touting, product comparisons, efficacy guarantees, and product association with medical institutions or organisations, and preclude the use of language that evokes fear of a disease or illness.

Product safety and liability

Moving even higher up the authoritative ladder, the State Council issued its *Special Provisions Regarding the Strengthening of Supervision and Administration of Food Products Safety* on July 25, 2007, which establishes China's first recall procedure for food and pharmaceutical products. On August 31, 2007, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) set up a system for tracking and recalling unsafe food and toys in the domestic Chinese market, as well as food and toy products for export (a system for recalling defective automobiles and

“MANUFACTURERS MUST STOP MAKING AND SELLING PRODUCTS THAT ARE CONSIDERED UNSAFE BY OTHER COUNTRIES' STANDARDS, EVEN IF THEY ABIDE BY CHINESE LAWS AND REGULATIONS.”

auto parts has been in place since October 1, 2005 and this served as a platform from which to build programmes in other sectors). Before last year, defective drug products were questionably subject to recall under Article 14 of the *Rules Regarding the Implementation of “Some Regulations on the State Supervision and Testing of the Quality of Products”* of February 2, 1987.

Now, the government can recall products that are dangerous or unapproved and issue consumer alerts. Manufacturers must stop making and selling products that are considered unsafe by other countries' standards, even if they abide by Chinese laws and regulations. Provincial and municipal authorities have also issued their own recall guidelines.

The protection of consumer rights has long been a cornerstone of the Communist Party's commitment to the welfare of the people. The *General Principles of Civil Law of the PRC*, effective since January 1, 1987; the *Product Quality Law of the PRC* of February 22, 1992; and the *Law of the PRC on the Protection of the Rights and Interests of Consumers* of October 31, 1993 all contain provisions relating to the protection of consumer interests and the liabilities for manufacturers and distributors of defective and dangerous goods.

An uncertain future

Last year, however, saw Beijing's first real commitment to removing dangerous goods from the market and penalising those responsible for the damage these cause. With the growing popularity of product liability insurance within the domestic food and pharmaceutical industries and the closing of non GMP-certified factories, the situation is meant to improve; however, recent events suggest this will take time.

Although more than a year has passed since the SFDA shake-up, the events of 2008 provide a stark reminder of how far China still needs to go. In April 2008, the Chinese-manufactured blood-

thinning agent heparin was found to be defective and responsible for at least four US deaths and hundreds of cases of allergic reactions globally, many serious. Investigations revealed that the factory, located outside Shanghai and owned by a US-based company, had never been inspected by the SFDA, although it had been approved by the US FDA for active pharmaceutical ingredient supply to the US. The recent melamine contamination is just one among numerous instances of shortcomings in the regulatory regime for both food and pharmaceutical products in China. As the country increases production to meet growing domestic demand and becomes more integrated into the global economy, the public outcry about these problems is sure to drive further strengthening of the existing regulatory system. Lawsuits lodged by Chinese against Chinese, as has happened in at least one of the recent melamine cases and in some of the Sichuan earthquake cases, is an indication of the growing public awareness in China of an individual's legal rights against unscrupulous traders, whose counterfeit or poor-quality products are now seen domestically as their own problem rather than someone else's.

Alan Adcock is deputy director of the intellectual property department of Tilleke & Gibbins in Bangkok. He can be contacted at: alan.a@tillekeandgibbins.com.



Alan Adcock

Alan Adcock has practised intellectual property law for 10 years, all of which has been exclusively devoted to practice in China and Hong Kong. Currently the deputy director of the intellectual property department at Tilleke & Gibbins in Bangkok, Alan's practice centres mostly on the commercial side, with experience in IP due diligence, acquisitions, technology transfer, clinical trial work and intellectual asset management. Alan has been named by *Asialaw* as a leading lawyer in the field of intellectual property for the past four years and recently co-authored the book *China Intellectual Property Challenges & Solutions: An Essential Guide* with Rebecca Ordish, senior IP counsel, Asia Pacific, at Cadbury.