China - compensation for drug and device-related injuries

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As China develops into one of the leading manufacturers for pharmaceutical and medical device products in the world, it must increasingly contend with what other nations have encountered over the past decades: finding the right way to compensate patients when they suffer from injuries that may have been related to the use of a drug or device product.

In the past decade, injuries caused by counterfeit and inferior drug and device products have grown in China, and injuries caused by adverse drug or device reactions have also soared. It is estimated that annually around 2.5 million patients are hospitalised and nearly 200,000 patients die in China due to adverse drug reactions (ADRs) (*Du Wenmin, A Study on Remedies and Compensation for Drug Injuries, in Study Report on Food and Drug Safety and Regulatory Policies (2008), 267, (Tang Minhao ed., 2008)*). In addition, in 2006, the State Food and Drug Administration of China (SFDA) received 369,392 ADR reports. In contrast, in 1988 when SFDA initially launched the ADR reporting programme, it received a little more than 500 ADR reports.

One notable factor contributing to the rise of ADRs in China is that an increasing number of drugs, both imported and domestically developed, are being marketed in China. (See, for example, *Ye Zhengming, Introduction to Compensation System for Adverse Drug Reactions in Foreign Countries and What China May Learn, in Presentday Law Science (Shidai Faxue), 93, 97, (2005-1)*).

Some compensation practices already exist in China, but they are neither uniformly applied nor subject to legal, regulatory or industry-sponsored guidelines. China faces complex policy considerations as it seriously considers implementing one or more overarching compensation schemes.

Against this backdrop, this article:

- Examines the drug/device-related injury compensation regime in China.
- Summarises compensation schemes in other jurisdictions.
- Reaches conclusions about the way forward for the Chinese compensation scheme.

THE DRUG/DEVICE-RELATED INJURY COMPENSATION REGIME IN CHINA

In China, drug and device-related injuries are perceived to be caused by counterfeit or inferior drug or device products, or by adverse drug or device reactions. Injuries caused by improper use of drug or device products by healthcare professionals during medical treatment are redressed through medical malpractice proceedings, and are not discussed in this article.

In Chinese law, Article 122 of the General Principles of the Civil Law and Chapter 4 of the Product Quality Law provide for compensation caused by defective products. Article 93 of the Drug Administration Law specifically provides for compensation for any injury to a drug user caused by a violation of this Law by a drug manufacturer, distributor or healthcare institution.

Chinese law does not employ a strict "no-fault" approach to determination of the liability of the manufacturer or distributor in drug and device-related injuries. In practice, the manufacturer or distributor is only liable for injuries caused by "defective" products. If a national or industry standard for a specific product exists, compliance with the standard will render the product not defective. Article 46 of the Product Quality Law states "for the purpose of this Law, a defect means…if a national or industry standard for a specific product exists, incompliance with such standard." Even when the product has a defect, if the manufacturer or distributor can prove that "the defect could not have been discovered when the product was put into commerce given the scientific and technology level at that time," it will not be held liable for any injury caused by the defective product (*Article 41, Product Quality Law*).

The current legal regime does provide certain protection to patients injured by counterfeit or inferior drug or device products. In relation to approved drugs, if the drug causing the injury was approved by the State Food and Drug Administration of China (SFDA) and conformed to the national or industry standard (if any), by statutory definition it is not defective. Adverse drug reaction (ADR) is defined as "adverse reactions that are caused by a drug that conforms to relevant standards when the drug is administered in normal dosage, and are either unrelated to the intended purpose of administering the drug or unexpected" (*Article 29.1, Rules on Reporting and Surveillance of Adverse Drug Reactions*). Therefore, injured patients are normally not entitled to any compensation. For example, in 2002, Longdan Xiegan Pill, a traditional Chinese medicine, caused acute renal failure in more than 140 patients. In litigation, the court rejected the patients' request for compensation on the ground that the drug was manufactured in conformity with the national standard in the Chinese Pharmacopeia. Such events have drawn wide criticism from the public.

Despite this legal framework, some Chinese courts have adopted the Equitable Liability doctrine in ADR compensation suits as an alternative to the fault-based liability doctrine. Under this doctrine, a court can order a manufacturer or distributor that has not committed any fault in the course of manufacturing or distribution to assume contributory liability for the damages that a consumer suffered, if the court deems it appropriate given the facts of the dispute (*Article 132, General Principles of the Civil Law*).

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For example, in 2000, a patient in Jiangxi Province brought a suit against a drug manufacturer, claiming that he developed encephalitis after taking a drug manufactured by the defendant company. The court found that the drug in question was manufactured in conformity with the national standard, and that the physician was not at fault in prescribing the drug to the patient; the cause of encephalitis was primarily the patient's physical idiosyncrasy. However, the court held that it would be unfair if the patient could not obtain any compensation and had to bear the very high encephalitis treatment expenses, and ordered that the drug manufacturer reimburse 30% of the treatment expenses to the patient.

In most cases, compensation for drug or device-related injuries is quite small. The patient is only entitled to recovery of the actual loss he suffered from the injury (*Article 44, Product Quality Law*), which is basically limited to the direct loss, and Chinese laws and judicial interpretations have established a fairly clear and rigid method for calculation of the direct loss. Chinese laws support compensation for mental damages (*Article 1, Interpretation on Application of Law in Suits for Personal Injury Damages, the Supreme Court of the People's Republic of China, 4 December 2003*), but the compensation amount may vary vastly among different courts and in most cases is nominal. Punitive damages are not recognised under Chinese law.

Since China does not have a common law system, judicial decisions have played a very minor role in how compensation decisions are made. Patients and manufacturers and distributors cannot look to judicial precedent as a firm basis for predicting the outcome of compensation decisions.

Due to the high cost of litigation and lack of certainty of the results, most compensation decisions are made through negotiation between a patient and a manufacturer or distributor. Such negotiation may be conducted either directly between the patient and the manufacturer or distributor, or through a mediation proceeding in which a local health agency officiates as the mediator.

Compounding the problem are a number of cultural and political realities that make a single, uniform system quite difficult:

- There are many political divisions at state, provincial, prefectural and county levels, that create very real differences in application or interpretation of the law.
- The country is essentially divided between close to one billion people living in a rural, low-income state, and an advanced urban-centred culture where prescription drugs and medical devices are quite common and there is usually a more educated population.
- At local levels, particularly in less developed regions, in litigation or mediation proceedings, courts or government agencies tend to favour drug manufacturers by minimising the compensation amount to avoid tax loss or unemployment.
- In most less developed regions, it is very difficult to set up a medical injury evaluation board consisting of professionally qualified and financially disinterested medical experts.

One of the primary objectives of the Chinese Central Government is to establish a fairer compensation system for patients who are allegedly injured after use of a drug or device product. However, based on an informal survey of drug and device companies operating in China, and participation in a working session intended to examine alternate means of compensation, it is quite clear to all concerned that the current system is unacceptable to the major stakeholders, that is, government, industry and patients.

There are no viable benchmarks for evaluating compensation in terms of severity of injury or duration of compensation, there are no benchmarks for the amount a patient should receive based on what patients and similarly situated settlements have received, and there is no process that prevents somebody from settling a claim and later seeking judicial redress.

The Shanghai Food and Drug Administration has taken a lead in considering the issues that would underlie pervasive legislation. Through the auspices of the Shanghai Institute of Food and Drug Safety, a recent seminar examined many of these policy issues and provided input from the many stakeholders whose interests are affected. What emerged immediately from these discussions was a shared interest in creating a system under which patients would have access to compensation for drug or device-related injuries, in a low-cost and time-efficient manner.

Among the various suggestions on the compensation system, one of particular note is the establishment of a nationwide adverse drug/device reaction compensation fund (*Gu Hai, Monitoring of Medical Device AERs and Lessons in Foreign Countries to Be Drawn, in Study Report on Food and Drug Safety and Regulatory Policies (2008), 364, 366, (Tang Minhao ed., 2008)*). Under this scheme, laws would be enacted to require drug/device manufacturers and distributors to make contributions to the fund in proportion to their sales volume. The Central Government and local governments would also make contributions to the fund, and the fund would also accept public donations. When an adverse reaction-related injury occurs, an independent board would review the injury and determine the compensation amount, and the patient would receive compensation from the fund. A drug/device manufacturer would be required to make a higher contribution to the fund if any compensation is paid from the fund as a result of an adverse reaction caused by the product it manufactures.

COMPENSATION SCHEMES IN OTHER COUNTRIES

Many compensation schemes currently exist, the scope of which range from global coverage systems to plans narrowly tailored to specified injuries. Most of the systems can be categorised as follows:

- Comprehensive compensation schemes, which provide either universal health insurance covering all medical expenses, or personal accident insurance covering personal injury expenses.
- Focused compensation schemes, covering injuries arising from medical treatment, including drug-related injuries and other specified injuries.
- A judicial tort system with either a negligence or strict liability standard.

The biggest difference between the first two and the last is the concept of "fault". "No-fault" systems attempt to make compensation faster and easier to access.

Focused compensation schemes represent by far the most common type of plan worldwide. The majority of these schemes are administered and funded by government agencies. While universal healthcare ensures that all citizens receive adequate medical care, for injuries and otherwise, it does not necessarily involve a corresponding compensation scheme. For example, while countries such as the UK and Canada provide national health insurance plans, no similar national injury compensation system exists in these countries.

Role of causation evidence

A central consideration in almost any system is how to decide who is responsible. It may be difficult for a patient to establish what drug or device he used. It may be difficult to prove that a counterfeit product was not the cause of the alleged injury. It may also be difficult or impossible to establish that some independent cause, such as a pre-existing condition was not the principal reason that a patient suffered harm.

A tort-based litigation system requires claimants to meet a demanding series of causation requirements before receiving compensation. Although no-fault schemes do not entirely remove the causation requirement, many have reduced burdens for proving causation, and some systems even presume causation.

For example, the National Vaccine Injury Compensation Program (NVICP) relaxes its causation requirement in specified instances by setting out a table of vaccines, associated injuries, and time periods by when the first manifestation of an associated injury must occur for a presumption of causation to arise (*Katherine E Strong, Note, Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day, 75 GEO. WASH. L. REV. 426, 437 (2007)*). One commentator has argued that by presuming causation in the case of "table claims", the NVICP essentially eliminates the causation requirement, particularly where scientific proof weakens the causal link but is not an available means to overcome the causation presumption (*Derry Ridgway, No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program, 24 J. HEALTH POL. POL'Y & L. 59, 61-62, 74 (1999), and at 63*).

New Zealand, Sweden, Finland and Denmark have developed comprehensive no-fault systems that eliminate proof of defendant's negligence, and which focus on timely and adequate compensation (*Marie Bismark and Ron Paterson, No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety, 25 Health Aff. 278, 279 (2006)*, noting the Royal Commission's scepticism about the ability of a liability-based system to provide financial support to injured accident victims unable to work).

New Zealand has essentially abolished its tort system for personal injuries and replaced it with a compensation system based on the concept of social insurance, designed to provide a means of financial support to accident victims who had lost their capacity to work (*Richard S Miller, An Analysis and Critique of the 1992 Changes to New Zealand's Accident Compensation Scheme, 52 MD. L. REV. 1070, 1071 (1993)* and *Bismark and Paterson, at 279*). Personal injuries are defined as death, physical injury, mental injury suffered because of physical injuries, mental injury resulting from certain criminal acts, or damages to dentures or prostheses. However, various types of personal injuries are excluded, unless they are work-related or the result of treatment (*Injury Prevention, Rehabilitation and Compensation Act*) (IPRCA).

Administered by a third-party government entity, the Accident Compensation Corporation (ACC) (*pt. 6, §165, IPRCA*) is funded through general taxation and an employer levy (*Bismark and Paterson, at 280*), and provides rehabilitation costs, compensation, and support for dependents (*pt. 4, § 69(1)(a)-(e), IPRCA*. See also *Bismark and Paterson, at 280-81,* describing entitlement categories).

Since its inception, New Zealand's compensation scheme has gradually shifted to a true no-fault standard. Although as of 1992 medical injuries required a showing of fault, by 2005 New Zealand had eliminated the fault requirement for claims relating to medical error.

In a broader approach to universal health care, Sweden, Finland, and Denmark have established no-fault compensation schemes for drug-related injuries. These systems also require some causation evidence by the injured party. Most of the funding is provided by pharmaceutical manufacturers or by taxes, and there are limits on liability.

Compensation schemes addressing specific injuries and products

There are many different approaches to compensating patients who were injured as part of clinical trials. In most countries, some element of consent is required, either under national laws or based on the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects 1964. The common theme in these informed consent provisions is full disclosure of the risks and benefits of the study and recognition by the patient of them, along with the availability of some type of treatment or compensation if a problem arises.

There are few countries that have established compensation for clinical trials other than Denmark and Finland. A couple of research institutions in the US have attempted to set a finite compensation scheme but that system has not been adopted by the government or made uniform throughout the country.

Vaccine compensation

One of the concerns particularly applicable to China is immunising a large population against diseases that could have devastating effects and are quite preventable. A number of countries have in place mandatory vaccination programmes for diseases such as diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps and rubella.

Many of the countries that have mandatory vaccinations also have vaccination legislation that provides for compensation for injured patients. A number of these schemes are funded by manufacturers, but most are government-funded, at least in part. Some of these countries require some proof of causation, particularly that the patient was administered the vaccine. For example, every US state mandates vaccinations for children entering public school. In contrast, although the province of Quebec (Canada) has a vaccine injury compensation programme, vaccinations are not mandatory in Canada.

TORT LITIGATION SYSTEMS FOR COMPENSATION

It is well-known that the court litigation system in the US has led to often incredible recoveries for patients, even where proof of causation was remote and liability practically limited to a small amount of money. The punitive damage system in the US permits, by its terms, "punishment" of a company for ignoring certain risks or placing patients at danger through inadequate warnings.

In practice, this system has led to forced settlements, often in billions of US dollars, and the creation of a legal industry based on obtaining classes of patients, many of whom may not actually have suffered the harm alleged in the case.

The two most common legal theories for this type of litigation are strict product liability and negligence. The essence of strict liability is that a medication or device is defective because of design, faulty manufacture or inadequate warning.

On the other hand, a negligence theory in pharmaceutical and medical device cases can be based on evidence that a manufacturer failed, with reasonably foreseeable foresight, to perform sufficient research into the safety or efficacy of its medication, to appreciate the significance of safety data showing the risk of specific side effects, or to promote its product in such a way to downplay its risks.

Other countries also use tort laws to compensate victims. In fact, many of the no-fault schemes discussed in this article exist within a broader, fault-based medical liability context, and the pursuit of litigation-based remedies is not always excluded because an individual has chosen to participate in the no-fault scheme. In some instances, however, the dual-recovery option may result in tension between the no-fault and fault-based avenues for redress.

The EU has imposed Directive 85/374/EEC on liability for defective products, which states that a producer is strictly liable for a defective product that causes injury to another, unless the producer can prove that it was not the manufacturer, that the defect was not its fault but rather required by government standards, or that it was state of the art at the time.

CONCLUSIONS

The authors conclude that the current system provides little guidance for manufacturers and distributors operating in China, whether domestic or foreign-based operations. Given that the Chinese Central Government is highly committed to establishing a uniform compensation system (as shown by, for example, the Shanghai Institute of Food and Drug Safety two-day seminar on post-marketing drug safety issues (29 and 30 October 2008) and working session, attended by government officials, academics, insurance company representatives, industry members and lawyers, including the authors), the authors believe that fundamental lessons can be derived from compensation systems in other countries.

Whether the ultimate choice in China is a single or combination methodology, whether it involves insurance or litigation, and whether it applies after an initial determination of causation, disproportionate recoveries must be avoided. They can create serious disincentives to innovation or to the maintenance of multiple sources for drug and device products.

Key components of a uniform compensation system can be gleaned from all the schemes discussed in this article, and can provide a footprint for China's consideration of a broad-based compensation scheme. They include:

- Administration by an autonomous government agency created for such purpose.
- Funding, at least in part, by the pharmaceutical industry, with potential for subsidies to be provided by the general public through taxation.
- Development of a comprehensive list of injuries according to which compensation will be provided (allowing for rapid resolution of individual cases, and uniform compensation for like injuries).
- Development of a similar list of the types of compensation to be provided (for example, medical expenses and lost wages), including a minimum threshold for eligibility, and limitations on total payout.
- Avoidance of fault-based requirements.
- Reduced burdens on causation (though some minimum threshold must be met).
- Inclusion of an opt-out provision to pursue compensation through the tort system (to deter very bad breaches of duty and human rights violations including, for example, unethical clinical trials).
- Right to appeal to the jurisdiction's legal system.

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