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Influence on Drug Manufacturers and Drug Distributors with Promulgation of the Tort Liability Law of the People's Republic of China (PRC)

This article presents the drug quality tort liability of drug manufacturers and drug distributors in China and reviews the related provisions of the Tort Liability Law.

by Ling Su

In China, the drug quality tort had been following the Product Quality Law of the People's Republic of China, which became effective on 1 September 2000. In order to protect the legitimate rights and interests of parties in civil law relationships, clarify the tort liability, prevent and punish tortious conduct, and promote social harmony and stability, the Tort Liability Law of the People's Republic of China, adopted at the 12th session of the Standing Committee of the Eleventh National People's Congress of the People's Republic of China on 26 December 2009, promulgated as Decree of the President of the People's Republic of China (No. 21), and on 1 July 2010. Since then, the drug quality tort liability of drug manufacturers and drug distributors has been clarified by the Tort Liability Law of the People's Republic of China instead of the Product Quality Law of the People's Republic of China. This article presents the definition and types of the drug quality liability in China, compares the difference of drug quality tort liability between the Product Quality Law of PRC and the Tort Liability Law of PRC, and attempts to illustrate the new provisions and amendments of drug quality tort liability for drug manufacturers and drug distributors, which have manufactured or distributed drugs in China since 1 July 2010.

Contents of Drug Quality Liability

In China, drug quality liability refers to the legal liability caused by any drug with potential safety risks, which are unreasonable risks to human health and life safety. Drug quality liability can be caused by a counterfeit drug, a substandard drug, or a qualified drug with potential safety risks found post-market.

Drug quality liability is divided into administrative liability, criminal liability, and tort liability. A drug manufacturer or a drug distributor which is at fault for infringement upon a civil right or interest of any drug customer should be subject to the tort liability. If a drug manufacturer or distributor should assume administrative liability or criminal liability for the same conduct, it also should legally assume the tort liability. If the assets of a drug manufacturer or distributor are not adequate for payments for the tort liability and administrative liability or criminal liability for the same conduct, the drug manufacturer or distributor shall first assume the tort liability.

In China, administrative liability is stipulated by the Drug Administration Law of the People's Republic of China and the Administration Measure on Drug Recall; criminal liability is stipulated by the Criminal Law of the People's Republic of China; and tort liability is stipulated by the Tort Liability Law of the People's Republic of China.

Assumption of Drug Quality Tort Liability

Tort Liability was clarified for the first time by the Tort Liability Law of the People's Republic of China. Tort Liability Law entitles the victim of a tort to require the tortfeasor to assume the tort liability. Whoever infringes upon civil rights and interests shall be subject to the tort liability according to the Tort Liability Law. The manufacturer or distributor shall be subject to the tort liability where a defective product

causes any harm to another person. For drug manufacturers or distributors, a defective product refers to a drug with potential safety risks; harm to another person refers to harm to human health and life safety.[1]

It is not stipulated in the Tort Liability Law, but is stipulated in the Product Quality Law and is still valid that the drug manufacturer shall not be liable for compensation if it can prove the existence of any of the following circumstances: 1. the drug has not been put in circulation; 2. the defect causing the damage does not exist at the time when the drug is put in circulation; or 3. the science and technology at the time the drug is put in circulation is at a level incapable of detecting the defect.[2]

If any drug with potential safety risks causes harm to human health and life safety, the drug manufacturer and distributor shall assume the tort liability. If the drug with ADR indicated in package insert or the drug mentioned on 1., 2., or 3. of the previous paragraph, causes harm to human health and life safety, the drug manufacturer and distributor shall not assume any tort liability.

In China, with regard to Traditional Chinese Medicine, the available techniques cannot fully explain the effective and harmful ingredients, and also cannot purify them. Based on the Tort Liability Law, if any drug manufacturer in China produced Traditional Chinese Medicine injection which results in new ADR or ADR already indicated in package insert, it need not assume any tort liability. For example, "Shuang Huang Lian Injection," "Acanthopanacis Senticosi Injection," "Heartleaf Houttuymia Herb Injection," and "Puerarin Injection" have caused ADR frequently for the past few years, but the drug manufacturers do not assume any tort liability.

Joint and Several Liabilities of Drug Quality Tort

Based on the Tort Liability Law, the drug manufacturer shall assume the tort liability where a drug with potential safety risks causes any harm to human health and life safety, and the drug distributor shall assume the tort liability where a drug with potential safety risks caused by the fault of the drug distributor causes any harm to human health and life safety. Where the drug distributor can neither specify the manufacturer nor the supplier of the drug with potential safety risks, the drug distributor shall assume the tort liability.[1]

Based on the Product Quality Law, where physical injury is caused to a person by a drug with potential safety risks resulting from the drug distributor's fault, the drug distributor shall be liable for compensation; where the drug distributor can neither identify the manufacturer of the drug with potential safety risks nor the supplier thereof, the drug distributor shall be liable for compensation. From the provisions mentioned above, the Tort Liability Law is based on the Product Quality Law in the joint and several liabilities of drug quality tort and are similar.[2]

The drug manufacturer and distributor have joint and several liabilities for drug quality tort, which is a special tort liability and is applicable to the principle of no-fault liability. For internal tort liability between the drug manufacturer and distributor, the drug manufacturer is applicable to the principle of no-fault liability, but the drug distributor is applicable to the principle of fault liability. In other words, the drug manufacturer shall assume the tort liability where a drug with potential safety risks causes any harm to human health and life safety. Whether the drug manufacturer has the fault or not; the drug distributor shall assume the tort liability only where a drug with potential safety risks caused by the fault of the drug distributor or the drug distributor can neither specify the drug manufacturer of the drug with potential safety risks nor specify the supplier of the drug with potential safety risks, then the drug distributor is concluded to have the fault and shall assume the tort liability.

For example, if any drug store sells counterfeit drugs or substandard drugs, the drug manufacturer shall assume the joint and several tort liabilities whether it has the fault or not. If any drugstore sells purposely counterfeit drugs, substandard drugs, or drugs without purchasing proof, according to the Tort Liability Law, the drugstore shall assume the tort liability.

Reimbursement of Drug Quality Tort Liability

According to the Tort Liability Law, where any harm is caused by a drug with potential safety risks, the victim may require compensation to be made by the drug manufacturer or distributor of the drug with potential safety risks. If the drug with potential safety risks is caused by the drug manufacturer and the drug distributor has made the compensation for the defect, the drug distributor shall be entitled to be reimbursed by the manufacturer. If the drug with potential safety risks is caused by the fault of the drug distributor and the drug manufacturer has made the compensation for the defect, the drug manufacturer shall be entitled to be reimbursed by the drug distributor.[1]

According to the Product Quality Law, where a drug with potential safety risks causes physical injury to a person, the victim may claim compensation from the drug manufacturer or the drug distributor of such drug. Where the drug distributor has made the compensation when it is the drug manufacturer that should bear the liability, the drug distributor shall have the right to recover the loss from the drug manufacturer. Where the drug manufacturer has made the compensation when it is the drug distributor that should bear the liability, the drug manufacturer shall have the right to recover the loss from the drug distributor. It is evident from the provisions mentioned above, the Tort Liability Law is based on the Product Quality Law in requirement and reimbursement of drug quality tort liability and are similar.[2]

It is stipulated definitely for the first time by the Tort Liability Law, where any harm to a patient is caused by the defect of any drug, medical disinfectant, or medical instrument, the patient may require a compensation from the manufacturer or require compensation from the medical institution. If the patient requires compensation from the medical institution, the medical institution that has paid the compensation shall be entitled to be reimbursed by the liable manufacturer.

The drug manufacturer, drug distributor, and medical institution have the parallel tort liability for the drug with potential safety risks; the victim may require entire compensation to be made by either the manufacturer, distributor, or medical institution, and do not consider the primary and secondary.

The medical institution shall assume the tort liability whether the medical institution had known the drugs could have potential safety risks. First, if the medical institution has not any fault, in the case of joint and several liabilities, only the medical institution shall be entitled to be reimbursed by the drug manufacturer, but the drug manufacturer shall not be entitled to be reimbursed by the medical institution. Second, if the medical institution has fault during the medical process simultaneously, the medical institution and drug manufacturer constitute a joint tort and shall assume joint and several liability; the compensation amounts shall be determined according to the fault degree of the medical institution or drug manufacturer; and if the fault degree of the medical institution or drug manufacturer can not be determined, the medical institution and drug manufacturer shall evenly assume the compensatory liability. The medical institution which has paid an amount of compensation exceeding its contribution shall be entitled to be reimbursed by the drug manufacturer, but the drug manufacturer which has paid an amount of compensation exceeding its contribution shall not be entitled to be reimbursed by the medical institution unless the medical institution has fault during the medical process.

For example, in April 2006, a medical institution in China found 64 patients who had used the "Armillarisin Injection," which was manufactured by the second Qiqihar Pharmaceutical Co., Ltd., suffered renal failure and 13 of whom eventually died. Guangdong Institute for Drug Control identified the "Armillarisin Injection" immediately, and determined that it used "diethylene glycol for industrial use" instead of "propylene glycol for medical use." Between July 2006 to June 2007, 11 victims (nine of whom died) and their families sued the medical institution, the drug distributors, the second Qiqihar Pharmaceutical Co., Ltd. and claimed up to a total of 2 million yuan ($309,023 USD[4]). On 26 June 2008, the First Instance Verdict demanded the second Qiqihar Pharmaceutical Co., Ltd. compensate 11 victims a total of more than 350 thousand yuan ($54,079 USD[4]), while the medical institution and the drug distributors should assume joint liability. The medical institution appealed that it is the first ADE report of "Armillarisin Injection," so the court should not equate the medical institution with the manufacturer and the drug distributors. The drug distributors appealed that the defendants should assume shared liabilitiy instead of joint liability, the victims' death was caused by three things, including their own disease, the counterfeit drugs involved, and improper treatment; therefore, claiming that the drug distributors should only assume the shared liability in accordance with the corresponding profit ratio for the injury consequences caused by the counterfeit drugs involved. On 10 December 2008, the Court of Second Instance upheld the first instance verdict. The Court of Second Instance considered that it is legal obligation for the medical institution to report in a timely manner to the relevant administrative departments after finding the serious adverse reaction of counterfeit drugs, and it is not the reason to be exempted from product quality tort liability. The Court of Second Instance also would not adopt the shared several liabilities, for the victims' death is caused by the counterfeit drugs involved, and there is no evidence that the victims' death is caused by the patients' own disease and the hospital's medical practice. On 9 January 2009, the victims applied for enforcement compensation from the medical institution. If based on the Tort Liability Law today, the court's decision is also correct. The victims may require compensation from any tortfeasor with compensation ability. If the medical institution has paid the compensation, it shall have the right to recover the loss from the second Qiqihar Pharmaceutical Co., Ltd.

Drug Quality Tort Liability of the Third Party

It is stipulated definitely for the first time by the Tort Liability Law that the drug manufacturer or drug distributor shall be entitled to be reimbursed by the third party. Where any harm is caused by a third party, the third party shall assume the tort liability. So where any harm is caused to a drug consumer by a drug with potential safety risks and the defect is caused by the fault of a third party such as carrier and so on, the manufacturer or distributor of the drug that has paid the compensation shall be entitled to be reimbursed by the third party.[1]

The drug manufacturer or drug distributor can not be exempt from the tort liability even though the defect is caused by the fault of a third party. The drug manufacturer or drug distributor pay the compensation first and are not entitled to be reimbursed by the third party unless the defect is caused by the fault of a third party. So in reality, the third party does not pay the compensation to the drug consumer directly and can not be indicted as the defendant.

For example, if any drug is contaminated during the logistics and distribution, basing on the Tort Liability Law, the drug manufacturer should pay the compensation first and then shall have the right to recover the loss from Logistics Company.

Tort Liability of Not Warning and Recalling

Based on the Administration Measure on Drug Recall, where a post-marketing drug with the potential safety risks is detected, a drug manufacturer should recall the drug with potential safety risks, and inform drug distributors or medical institutions to stop selling and using the drug with potential safety risks. Where a drug manufacturer does not recall the drugs with potential safety risks, no matter what is decided initially or ordered passively by drug regulation department, it shall be ordered to recall the drugs. Three times the value of the drugs also shall be imposed. If the circumstances are serious, the drug approval documents shall be withdrawn by the original certification department. Even the Drug Manufacturing Certificate shall be revoked. Where a drug manufacturer does not inform the drug distributors or medical

institutions to stop selling and using the drugs with potential safety risks after it makes a decision to recall the said drugs, the drug manufacturer shall be given a disciplinary warning and shall be instructed to rectify within a time limit. If it fails to do so, the drug manufacturer shall be fined 30,000 yuan[3] ($4,635 USD[4]).

According to the Administration Measure on Drug Recall, where a post-marketing drug with the potential safety risks is detected by a drug distributor or medical institution, it should stop selling and using the drug with the potential safety risks, inform the drug manufacturer or supplier, and report to the drug regulation department. If it fails to do that, it shall be ordered to stop selling and using the drugs; a fine not less than 1,000 yuan ($154 USD[4]), but not more than 50,000 yuan ($7,725 USD[4]) shall be imposed.[3]

It is stipulated definitely for the first time by the Tort Liability Law, that the drug manufacturer or drug distributor shall assume the tort liability for not timely warning and recalling the drug with potential safety risks. Where any drug with potential safety risks is detected after the drug is put into circulation, the drug manufacturer or drug distributor shall take remedial measures as warning and recall in a timely manner. The manufacturer or distributor which fails to take remedial measures in a timely manner or take sufficient and effective measures and has caused any harm shall assume the tort liability.[1]

According to the Product Quality Law, the drug manufacturer shall not be liable for compensation if it can prove the existence of the science and technology at the time the drug is put in circulation is at a level incapable of detecting the defect. This provision is unfair for the victims, and the drug manufacturer can take advantage of it and be exempt from the tort liability easily. The Tort Liability Law limits the exception clause stipulated on the Product Quality Law.[2]

The drug manufacturer or drug distributor shall not assume the tort liability if it takes necessary, timely, reasonable, and effective remedial measures, for in such a case, the damage can be considered an accident instead of the fault of the manufacturer or distributor.

For example, in 2000, a drug manufacturer found that "Manchurian Dutchmanspipe Stem" has serious renal toxicity which is the ingredient of "Long Dan Xie Gan Pill," and reported to the drug regulatory authorities that "Aristolochic Acid" can cause renal injury. On 1 April 2003, the State Food and Drug Administration of China issued "Notice on cancellation of the Manchurian Dutchmanspipe Stem pharmaceutical standard." The "Notice" cancels the "Manchurian Dutchmanspipe Stem" pharmaceutical standards; and demands the drug manufacturers of "Long Dan Xie Gan Pill" series product replace "Manchurian Dutchmanspipe Stem" with "Akebia Stem (without Aristolochic Acid)" before 30 April 2003; and other drug manufacturers which use "Manchurian Dutchmanspipe Stem" do that before 30 June 2003. The Pharmacopoeia of People's Republic of China 2005 deleted the Manchurian Dutchmanspipe Stem. So the drug manufacturer was not required to assume any tort liability for their "Long Dan Xie Gan Pill" manufactured before 30 April 2003, but if according to the Tort Liability Law and Administration Measure on Drug Recall now, the drug manufacturer must suspend manufacturing and selling and recall the "Long Dan Xie Gan Pill" after finding the drugs with renal toxicity, otherwise it shall assume Tort Liability.

Tort Liability of Punitive Compensation

It is stipulated definitely for the first time by the Tort Liability Law that the drug manufacturer or drug distributor shall assume a punitive compensation. Where a drug manufacturer or drug distributor knowing any drug with the potential safety risks continues to manufacture or distribute the drug and the defect causes a death or any serious damage to the human health, the victim shall be entitled to require the corresponding punitive compensation.[1]

Punitive compensation is applicable under the following conditions: 1. the manufacturer or distributor has subject intent; 2. serious damage to the human health or life safety; and 3. causality between defect and serious damage. But answers to the following questions: "What is punitive compensation?" and "How much shall be the punitive compensation?" are not stipulated on Tort Liability Law. It is important to pay close attention to relevant judicial interpretations enacted subsequently.

Now China still has no case of tort liability of punitive compensation. According to the Tort Liability Law now, if the drug manufacturer mentioned above knows the "Long Dan Xie Gan Pill" with renal toxicity, but does not suspend manufacturing and selling and recall the drugs, it also shall assume a punitive compensation.

Mitigation and Exemption of Drug Quality Tort Liability

It is stipulated definitely for the first time by the Tort Liability Law that the tort liability of the drug manufacturer or drug distributor shall be mitigated or exonerated. Where the victim of a tort is also at fault as to the occurrence of harm, the liability of the drug manufacturer or drug distributor may be mitigated. The drug manufacturer or drug distributor shall not be liable for any harm that is caused intentionally by the victim.[1]

The drug manufacturer or drug distributor has the burden of proof. In other words, the liability of the drug manufacturer or drug distributor shall not be mitigated or exonerated, unless it can prove that the victim is also at fault as to the occurrence of harm or the harm is caused intentionally by the victim.

For example, if the drug manufacturer can prove that the injury is caused by not following the dispensatory purposely, such as overdose, incompatibility, or precautions, the tort liability of the drug manufacturer shall be mitigated or exonerated.

Compensation Contents of Drug Quality Tort Liability

According to the Tort Liability Law, where a tort causes any personal injury, the drug manufacturer or drug distributor

shall compensate the victim for the reasonable costs and expenses for treatment and rehabilitation, such as medical treatment expenses, nursing fees and travel expenses, as well as lost wages. If the victim suffers any disability, the drug manufacturer or drug distributor also shall pay the costs of disability assistance equipment for the living of the victim and the disability indemnity. If it causes the death of the victim, the drug manufacturer or drug distributor also shall pay the funeral service fees and the death compensation.[1]

According to the Product Quality Law, where physical injury is caused by defects in a product, the person liable shall compensate the victim for the expenses of medical treatment, expenses of nursing care during treatment, and the decreased earnings due to the loss of his working time; where the victim is disabled, the person liable shall, in addition, pay for the self-care equipment, subsistence allowances, disability compensation to the victim, living expenses necessary for any other person(s) supported by the victim, etc. Where such defects cause death to the victim, the person liable also shall pay for the funeral expenses, compensation for death, and the living expenses necessary for any other person(s) supported by the deceased before his death, etc.[2]

Tort Liability Law is based on the Product Quality Law in compensation contents of drug quality tort liability, but it is a wonder that the living expenses necessary for any other person(s) supported by victim is not mentioned in the Tort Liability Law. It is important to be aware of relevant judicial interpretations enacted subsequently.

For example, on 27 May 2005, Miss Wang Xiaohua, the victim of "Long Dan Xie Gan Pill," received the first "Long Dan Xie Gan Pill" Compensation verdict in China. The verdict identified that the prosecutor, Miss Wang Xiaohua from Inner Mongolia Autonomous Region had purchased and used the "Long Dan Xie Gan Pill" which was distributed by the defendant, and it has clear verity and sufficient evidence to support that prosecutor's renal injury is caused by "Long Dan Xie Gan Pill." The verdict supports all the claims of the prosecutor and demand the drug distributor compensate 39,304 Yuan ($6,072 USD[4]) to the prosecutor. If based on the Tort Liability Law today, if the drug distributor had paid the compensation, it would have had the right to recover the loss from the drug manufacturer, but at that time, this claim was not submitted.

Influence on Global Drug Manufacturers with Promulgation of the Tort Liability Law

After implementation of Tort Liability Law of the PRC, the victims have rights to claim compensation freely from drug manufacturers, medical institutions, or drug stores. In China, the patients tend to choose medical institutions or drug stores from which they bought drugs directly to claim compensation. After paying the compensation, if the medical institution or the drug store has not any fault, it shall be entitled to be reimbursed by the drug distributor or the drug manufacturer which has fault; if the medical institution, the drug store or the drug distributor has fault and the drug manufacturer has not any fault, the drug manufacturer may not pay the compensation. It can reduce the various activities in civil litigation claim for global drug manufacturer in China.

The global drug manufacturers which import and sell drugs to China should consider the following aspects:

First, strengthen drug quality control of distributors in China. Global drug manufacturers should be very careful to select the respected distributors in China. Global drug manufacturers also should reduce the fault made by drug wholesalers and drug retailers as much as possible which may cause ADE or any other drugs quality problems, and thus avoid responsibility for no-fault joint and several liabilities.

Second, strengthen recall management of the drugs with potential safety risks. Global drug manufacturers should develop an efficient drug recall system to ensure drug recall successfully, and thus avoid the tort liability of punitive compensation because of failure on drug recall.

Third, ensure the truthfulness and comprehensive of contents in the package insert. Global drug manufacturers should standardized the written form and content of package insert, especially should pay attention to dosage, precautions, ADR, contraindications, and try to avoid the tort liability for the injury caused by patients' misunderstanding on package insert, and mitigate or exempt the tort liability for the injury caused by patients' intentional and negligent action.

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4. Used USD exchange rate as of 21 June 2011.

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