INSIGHT

Cross-border product liability claims

Sanjay Kumar, Counsel, J Sagar Associates, sheds light on how globalisation has led to a blurring of boundaries, and, thus, with tremendous product circulation and exchange, the need to a harmonised system for cross-border litigations is felt not more than ever

Globalisation has led to the proliferation of product liability laws and standards worldwide with an increase in cooperation and information sharing among countries in governmental action and investigations against pharmaceutical companies. The spread of collective redressal mechanisms and growth of third-party funding of litigation costs has caused an increase in regulatory interplay among nations. For example, off-label promotion investigations and adverse drug reactions have produced significant class-action litigations, including Zyprexa, Risperdal, Seroquel, Neurontin, Avandia, Actiq and many others.

Global trends in product liability litigation

Product liability is the area of law in which manufacturers, distributors, suppliers, retailers, and others who make products available to the public, are held responsible for the injuries those products cause. Liability in such scenarios arises in case of manufacturing defect of the product, deficiency in services relating thereto or failure to warn recipients of the known drug reactions. The substantive test for medicinal product liability that has gained prominence in light of the import of vaccines, COVID-19 drugs (Remdesivir), is largely based on whether the medicinal product that is manufactured, distributed, stocked or sold is spurious, adulterated, counterfeit, not of standard quality, or is in any way in violation of the Drugs and Cosmetics Act, 1940 or causes (or is likely to cause) harm to the general public. Given the expediated and emergency approvals enabled in light of the pandemic for import of vaccines, manufacturing and use of COVID-19 drug, the exposure of such manufacturers is increased to product liability claims.

Such claims are brought within the ambit of product liability under the product liability laws, law of torts and consumer-protection laws in various countries, including in India.

In the US, foreign drug manufacturers have experienced a general increase in the claims outside their jurisdictions due to numerous factors including the increased awareness among individuals regarding product quality and claim mechanism. Since products are supplied globally, claims may be brought under numerous jurisdictions with respect to the same product, leading to multiple claims. In light of it, various countries undertake exchange of information, documents, witness statements, etc. to ease the settlement of such claims by the courts which have enabled blurring of stringent boundaries in litigation procedures worldwide and have enabled flexibility in such processes in terms of multiple or class action suits.

Product liability suits

In most countries, any recall or withdrawal of products by manufacturers, either statutory or voluntary, assumes defect in product as the cause for withdrawal; while claims of defective product made by individuals may cause chaos in the trust placed by the shareholders in the product leading to shareholder suits in light of the potential liability and similar disputes by interested parties.

Risks of potential suits exist in light of the early marketing of new drugs upon basing heavy

reliance on post-marketing trials and reporting. These arise upon the occurrence of non-identified or notified drug reactions. Such claims are most often covered under specific statutes pertaining to the product liability; although, in the absence of such statutes, claims falling beyond the scope of product liability are entertained by courts on the basis of jurisdiction as numerous countries link such civil claims with criminal proceedings. On the contrary, some countries lack specific legislation in this regard and bring product liability claims under regular suits.

Product liability claims in India are covered under the Consumer Protection Act, 2019 for defect in product or services relating thereto. Unless the same is proved, the statute refuses to impose liability on the parties. Thus, in cases of drug reactions which have not been notified by the manufacturer, these are failed to be brought within the ambit of CPA, and are largely dependent on pharmacovigilance reports by the manufacturers undertaking post marketing surveillance.

Interplay of regulatory compliance and litigation

Statutes impose liability on manufacturers for defect in product or services offered in relation thereto, in addition to consumer protection claims. While numerous manufacturers claim immunity from liability in terms of being in compliance with the regulatory requirements, litigation instituted against them necessitates a co-ordinated redressal. For instance, the FDA approval in the USA to certain products assumes regulatory compliance, and requires no pre-emption against the manufacturer. In case of any claims against such approval, warning letters are issued by the FDA which are not conclusive for the purposes of litigation reliefs. Thus, a constant battleground situation continues to pertain.

Exceptions to product liability claims allow pre-emption to generic products. A possibility of pre-emption for design defect claims in products, claims of warnings being negotiated with regulators is no defence while limited defence is available under the product liability directive if the defect is due to failure in compliance with mandatory requirements. It has been observed by the regulatory authorities that grant of marketing authorisation to products does not automatically provide for immunity against liability and claims may still be entertained by the authorities.

Certain defences pertaining to defect not known or discoverable at the time when product is put into circulation based on scientific/technical knowledge, have a limited scope, and are rarely successful in the court of law. Although, manufacturers continue to claim immunity against claims for failing to warn about risk that was unknown at the time.

In re Zantac (Ranitidine) product liability litigation, we witnessed the court examine innovator liability in a multidistrict litigation (MDL) that sought damages under the laws of fifty states with varying outlook on product liability claims. The FDA requested its removal from the market because of a new risk discovered more than thirty years after the drug was first approved. This led to a statutory product recall of the drug from the US and a voluntary recall from India by the manufacturers situated in England after the regulators asked GSK to check its products for carcinogen.

Conclusion

Globalisation has led to a blurring of boundaries, and with tremendous product circulation and exchange, the need to a harmonised system for cross-border litigations is felt not more than ever. There has been an increase in the number of claims exported from the US, which has triggered claims worldwide. To erode the barriers to cross border litigations in the US and countries beyond, authorities must act in unison and cooperate.

Cross Border litigations require an exchange of information, documents and data pertaining to the claims raised in the domestic courts or regulatory bodies in order to enable efficiency in access to justice to the claimants, while some jurisdictions may impose restrictions on transfer of documents which may be resolved by complying GDPR or country-specific data-protection law.

The views expressed in this publication are personal and are not the views of the firm.