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THE LEGAL SPREADSHEET

PRODUCT LIABILITY IN INDIA

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- SUPREME COURT BACKS THE RIGHT TO EDUCATION ACT

Your View

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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 caused due to their products.

In India, there is no specific statute governing pharmaceuticalproduct liability however the law governing product liabilities could be ascertained under the following enactments:

1. The Consumer Protection Act, 1986;
2. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945;
3. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955;
4. The Legal Metrology Act, 2009 and the Legal Metrology (Packaged Commodities) Rules, 2011;
5. The Indian Contract Act, 1872;
6. The Sale of Goods Act, 1930;
7. Law of Torts.

Each of the above statutes is briefly discussed below:

Consumer Protection Act, 1986

The Consumer Protection Act, 1986 ("CPA") was enacted to provide for better protection of the interests of consumers and to establish the consumer councils and other authorities for settlement of consumers' disputes and for matters connected therewith.

Under the CPA,a complaint in relation to the goods soldor to any service can be filed by the complainant with the appropriate forum i.e. either District Forum or State Commission or National Commission, depending upon their respective pecuniary jurisdictions. Complaint by a consumer / complainant is the first step which commences action under the CPA.

Upon a complaint being made, the appropriate forum will hear and dispose off the complaint in terms of the CPA. After the proceeding, if the forum is satisfied that the goods complained against suffer from any of the defects specified in the

complaint, it shall issue an order to the opposite party directing to do one or more of the following things, inter alia, removing of the defect, replacing the goods, returning the price or the charges paid by the complainant, to pay compensation, to discontinue the unfair or restrictive trade practice, to withdraw the hazardous goods from being offered for sale, etc.

In the event if a person against whom a complaint is made fails or omits to comply with any order made by the appropriate forum, such personshall be punished with an imprisonment of not less than one month but which may extend to three years; or pay a fine of, not less than, Rs.2,000/- but which may extend to Rs.10,000/- or both.

Orders of District Forum are appealable to the State Commission and that of State Commission to the National Commission and the final appeal lies with the Supreme Court.

The CPA defines the term complaint to mean any allegation in writing complaining inter aliaabout an unfair trade practice, a restrictive trade practice, defective goods or deficiency in service and the term complainant under the CPA inter alia can be one or more consumers, registered voluntary consumer association, the Central or State Government and in case of a death of a consumer, his legal heir or representatives.

The CPA also defines the term consumer and it not only includes the buyer who purchases the goods but also the user when such use is made with buyer's approval.

The CPA also defines various other important terms including but not limited to unfair trade practice, restrictive trade practice, defect, trader, manufacturer, etc.

It should also be noted that remedies provided under CPA are in addition to the remedies provided under other statutes.

Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act 1940 (**"DCA"**) was enacted to regulate the import, manufacture, sale and distribution of drugs and cosmetics. Regulatory control over the quality of drugs in the country is exercised by both the Central and State Governments through the provisions of the DCA.

The DCA provides for restrictions on the importing, manufacturing, selling, stocking or exhibiting the drug which *inter alia* is a misbranded, adulterated, spurious drug or a drug which is not of a standard quality.

Any contravention of the provisions of the DCA is punishable under the DCA. The punishment ranges from imprisonment from 6 months up to 5 years and fine from Rs. 500/- to Rs. 10,000/- depending upon the type and gravity of the offence.

However in cases of import and/ or manufacture of any drug deemed to be adulterated or spurious under the DCA and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease/ disorder is likely to cause his death or harm on his body as would amount to grievous hurt within the meaning of Section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not of standard quality shall be punishable withimprisonment which is not less than 10 years extendable to life imprisonment and fine which shall not be less than Rs. 10,00,000/-or three times value of the drugs confiscated, whichever is more. Such fine imposed on and released from, the person convicted (in case of his death his relative) shall be

paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in the relevant section.

On subsequent conviction under provisions of DCA, the person shall further be liable to be punished with enhanced penalty of imprisonment from 2 years to life imprisonment and penalty ranging from Rs. 2,000/- to Rs. 2,00,000/-.

Drugs and Cosmetics Rules, 1945

The Drugs and Cosmetics Rules, 1945 (**"DCR"**) have been issued under the DCA. DCR lays down numerous rules to be adhered to by the importer / manufacturer, such as obtaining of import license, prohibiting the import of biological/ special product after expiry of potency of the drug, prohibiting the import of drugs into India in the event the manufacture, sale or distribution of such drug are prohibited in the country of origin, compliance to prescribedstandard by imported drugs, imported drugs to be accompanied by an invoice having the name and address of the manufacturer and such other compliances as encapsulated in the DCR including the labelling requirement as provided in DCR.

Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954("DMR") and the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955("Rules")

DMR and Rules wereenacted to control the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith. It also tackles false and misleading claims.

DMR prohibits advertisement of certain drugs for treatment of certain diseases and disorders. It restricts any person from taking part in publication of any advertisement referring to any drug which suggest or lead to use, inter alia, the diagnosis, cure, mitigation, treatment or prevention of any disease or conditions specified in the Schedule to the DMR or such other disease, disorder which may be specified in the rules made under DMR.

DMR further prohibits the publication of misleading advertisements relating to a drug which gives a false impression or makes a false claim or is misleading in nature.

DMR also provides for prohibition of import into, and export from India of certain advertisements and states that no person shall import into, or export from, the territories to which the DMR extends any document containing an advertisement of the nature restricted under DMR.

In the event of any contravention of the provision under DMR and the Rules, the person who contravenes shall on first conviction, will be punishable with imprisonment which may extend to 6 months, or with fine, or with both and for a subsequent conviction, with imprisonment which may extend to 1 year, or with fine, or with both.

The Rules also empower the Customs Collector to detain and dispose of any consignments which contain advertisements or documents relating to diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition

specified in the Schedule or which gives a false impression or makes a false claim oris otherwise false or misleading in any material particular.

Legal Metrology Act, 2009

With a view to provide a coherent scheme and uniform standards of weights & measures, the erstwhile Act namely Standards of Weights & Measures Act, 1956 was enacted. Apart from it, the Standards of Weights and Measures Act, 1976 provided for establishing standards of weights and measures. It also became necessary to keep the regulation pragmatic to the extent required for protecting the interests of consumers and at the same time keep the industry free from undue interference. Thus keeping the above in mind the Legal Metrology Act, 2009 (hereinafter referred to as the **"LMA"**) was enacted and came into force on 1 April 2011.

LMA prohibits any person, in relation to goods,to quote any price or publish any advertisement or indicate the net quantity of a pre-packaged commodity or express in relation to any transaction, any quantity or dimension which shall not be in accordance with the standard unit of weight, measure or numeration as provided under LMA.

LMA also provides that no person shall manufacture, pack, sell, import, distribute, deliver, offer, expose or possess for sale any pre-packaged commodity unless such package is in such standard quantities as prescribed and any advertisement mentioning the retail sale price of a pre-packaged commodity shall contain a declaration as to the net quantity in such form as prescribed.

In the event of contravention of the provisions of LMA, various penalties are prescribed for depending upon the nature of the contravention an imposition of fine from Rs. 2,000/- to Rs. 1,00,000/- and / or with an imprisonment from 3 months to 1 year.

Legal Metrology (Packaged Commodities) Rules, 2011

The Legal Metrology (Packaged Commodities) Rules, 2011 ("LMR") provides for the requirements that need to be satisfied when goods are sold through retail, wholesale or through import and export channels.

The rules under LMR have been categorized into various chapters viz. provisions applicable to packages intended for retail sale, wholesale packages, export and import of packaged commodities and registration of manufacturers and packers.

The LMR provides for various compliances such as affixing label with prescribed declaration as provided under LMR for any products that are pre-packaged, sold, distributed, and stored for sale.

In the event of any contravention of any provisions of the LMR then such person shall be punished with fine ranging from Rs. 2,000/- to Rs. 4000/-.

Indian Contract Act, 1872 and Sale of Goods Act, 1930

The Indian law relating to sale of goods is codified under two pieces of legislations viz. Indian Contract Act, 1872 ("ICA") and Sale of Goods Act, 1930

("SGA").

ICA is the main source of law regulating contracts in India. The ICA defines the term contract as "any agreement enforceable by law". The ICA is the law of agreements which create obligations, and in case of a breach of a promise by one party to the agreement, the other has a legal remedy.

SGA is one of the oldest statutes governing mercantile law. The SGA is complimentary to the ICA. Basic provisions of ICA apply to contract of sale of goods also. The SGA lays down special rules of law which are peculiar to sale of goods. It provides for various implied conditions and warranties on the part of the seller breach of which provides for cause of action to the consumer. The SGA contains no penal provisions nor does it lay down any special rules of evidence or procedure.

Under the ICA, the party who suffers loss on account of breach of a contract by the other party is entitled to receive from the party who has breached the contract, compensation for any loss or damage caused to it which naturally arose in the usual course of things from such breach or which the parties know when they made the contract to be likely to result from the breach of it. However no compensation is to be given for any remote and indirect loss of damage sustained by reason of the breach.

The ICA deals with the general law pertaining to contracts entered into between the parties for a particular purpose while SGA deals with contracts pertaining to the contracts for sale of goods between the parties. In terms of Section 3 of the SGA the provisions of ICA will continue to apply to such contract of sale of goods provided that there are not inconsistent with the express provisions of the SGA. However as a general rule the circumstances under which damages may be awarded are stated in the SGA while the measure of damages is to be determined in accordance with the provisions of ICA.

Law of Torts

Tort is a civil wrong other than a mere breach of contract or breach of trust. Under tort unliquidated damages are the most important remedy. As per common law principles, claims in relation to negligence may be brought if it can be shown that there was a breach of a duty to take care and an injury or loss resulted from such breach. In case of faulty goods, claims may be brought against traders, in addition to the manufacturer, if the fault is attributable to the trader.

Conclusion

Non-compliance or non-observance of the provisions of the aforementioned statutes may amount to action from the regulatory authorities, consumers or any other entity having cause of action.

Note: This article is restricted to enlightening the readers on the general law of product liability and should not be construed as an opinion on compliances under the respective statutes.

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