International
Comparative
Legal Guides

Drug & Medical Device Litigation 2021

A practical cross-border insight into drug & medical device litigation

Second Edition

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1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

In India, the legislative and regulatory bodies regulating pharmaceuticals, medical devices, etc. operate under the aegis of the Ministry of Health and Family Welfare and the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers. Various bodies have been constituted to regulate various aspects of pharmaceuticals, medical devices, etc., principal amongst which are listed hereinbelow:

- **Ministry of Health and Family Welfare (MoHFW)** – The MoHFW is an Indian Government ministry charged with health policy in India. It is also responsible for all Government programmes relating to family planning in India. It sits at the helm of regulatory bodies and committees relating to drugs, medical devices, etc.
- **Central Drugs Standard Control Organization (CDSCO)** – Under the Drugs and Cosmetics Act, 1940 and Rules, 1945 (DCA), CDSCO is responsible for approval of drugs, conduct of clinical trials, laying down the standards for drugs, control over the quality of imported drugs in the country, and coordination of the activities of State drug control organisations by providing expert advice with a view to bringing about uniformity in the enforcement of DCA. Further, CDSCO, along with State regulators, is jointly responsible for granting licences of certain specialised categories of critical drugs, such as blood and blood products, intravenous (IV) fluids, vaccines and sera.
- **Indian Council of Medical Research (ICMR)** – ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research and is one of the oldest medical research bodies in the world.
- **Indian Pharmaceutical Association (IPA)** – IPA is a national body representing over 1 million pharmacists and pharmaceutical scientists from industry, academia, regulatory, hospital and community pharmacy and works to meet India's healthcare needs.
- **Drug Technical Advisory Board (DTAB)** – DTAB is constituted by the Central Government to advise both them and the State Governments on technical matters arising out of the administration of DCA and to carry out other functions set out under DCA.
- **Drugs Consultative Committee (DCC)** – DCC is an advisory committee that advises the Central Government, the State Governments and DTAB on any matter tending to secure uniformity throughout India in the administration of DCA.
- **Central drug testing laboratories** – These laboratories can be found in Chandigarh, Chennai, Guwahati, Hyderabad, Kasauli, Kolkata and Mumbai. They provide analytical quality control of the majority of imported and domestic drugs and cosmetics. The laboratories at Chennai, Kolkata and Mumbai act as Appellate Authority in disputes relating to the quality of drugs.
- **Indian Pharmacopoeia Commission (IPC)** – IPC is an autonomous institution of the MoHFW. IPC was created to set standards of drugs in India and to regularly update the standards of drugs commonly required for treatment of prevailing diseases.
- **National Pharmaceutical Pricing Authority (NPPA)** – NPPA implements and enforces the provisions of the Drugs Price Control Order in accordance with the powers delegated to it. It also undertakes and/or sponsors relevant studies in respect of pricing of drugs/formulations; monitors the availability of drugs, identifies shortages, if any, and takes remedial steps; collects/maintains data on production, exports and imports, market share of individual companies, profitability of companies, etc. for bulk drugs and formulations; and renders advice to the Central Government on changes/revisions in the drug policy, etc.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

Liabilities for injuries suffered because of product use, or marketing and sale of the product, arise from two situations. In one situation, an injury does not necessarily occur, but the liability is attached to the manufacturer or the seller if the product is defective. In another situation, an actual injury does occur due to the use or marketing and sale of a product.

DCA, the Consumer Protection Act, 2019 (CPA) and the Indian Penal Code, 1860 (Penal Code) prescribe penalties for manufacturers and sellers of any drug, cosmetic or medical device that contravene the manufacturing and sale requirements under DCA, or if such products are otherwise adulterated or spurious. Penalties include imprisonment and a fine.

In cases where there has been an actual injury to a user, liability arises under CPA and the user of a defective/spurious product may seek damages against the manufacturer and seller.

In case of any bodily injury suffered by a user due to a spurious or adulterated product, the manufacturer and seller may be penalised under the Penal Code.

Even for misleading advertisements, hefty penalties may be imposed on a manufacturer/seller under CPA provisions. Advertisements in India are regulated by the Advertising Standards Council of India (ASCI) and complaints of misleading advertisements made to ASCI are escalated to the Consumer Complaints Council under CPA, which may take necessary action.

There is no law that provides that approval of a product by the regulators gives immunity or protection from liability.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

The regulation of life sciences products, especially those falling under DCA, impacts litigation involving such products by bringing in various mechanisms of checks and balances. DCA lays down stringent provisions to cull adulterated and spurious drugs and paves the way to a uniform system of control over pharmaceuticals, medical devices, etc. in India. On the other hand, to avoid frivolous complaints under DCA, it mandates that complaints can only be filed by drug inspectors appointed under DCA for inspecting the premises of manufacturers/sellers and quality of products or by an aggrieved person or recognised consumer associations.

Approval of a product by the regulators might not give blanket protection from liability to a manufacturer or seller of a life sciences product, but it may provide a good defence against a complaint filed under CPA or the Penal Code. Needless to say, the product alleged to have caused injury should have complied with the regulatory approval.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

There are but a few self-regulatory bodies that govern drugs, medical devices, supplements, etc. However, these bodies are constituted as associations and the codes of conduct and other guidelines implemented by these associations have assertive power only over their members and stakeholders.

Although these bodies do not directly affect litigation and liability involving such products, they provide a platform for addressing grievances and voice the concerns of their stakeholders before the Government. The Government considers the comments, suggestions and advice of these self-regulatory bodies while designing policy framework and drafting rules that go on to govern pharmaceuticals, medical devices, etc.

Some of the self-regulated bodies (associations) in India that govern drugs, medical devices, etc. are as follows:

- Indian Internet Pharmacy Association (IIPA).
- Federation of Indian Chambers of Commerce & Industry (FICCI).
- IPA.
- Organization of Pharmaceutical Producers of India (OPPI).
- Indian Medical Association (IMA).
- Consumer Online Foundation, New Delhi.
- Pharmacy Council of India (PCI).
- All India Organization of Chemists and Druggists (AIOCD).
- All India Drug Control Officers' Confederation (AIDCOC).

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Life sciences companies provide information on their products through carton/container labels and through package inserts. While the container labels are aimed to directly inform the consumer, the package inserts are targeted towards medical practitioners (learned intermediaries).

The labelling information required on container labels is governed by Rules 96 and 97 DCA. The container labels are not required to provide warnings of the risks of their products directly to the consumer. Having said that, Rule 97 prescribes certain caution statements to be present on labels for different drugs categorised in different schedules, as given below:

- Schedule H, X and H1 drugs are required to have the warning: "To be sold by retail on the prescription of a Registered Medical Practitioner only."
- For Schedule H1 drugs, there is an additional warning: "It is dangerous to take this preparation except in accordance with the medical advice."
- In addition to the above, Schedule H, X, H1 and narcotic drugs are to be labelled as **Rx**, **XRx**, **Rx** and **NRx**, respectively.

The package inserts are governed by Section 6, Schedule D-II DCA and the inserts are required to provide therapeutic indications, special warnings and precautions, contraindications, undesirable effects, etc. The package inserts are required to be in English and, given their complexity and problems of comprehension, the same are therefore not consumer-friendly but aimed to educate medical practitioners only.

In India, as of now, drugs can be sold only via prescription, although DCC is setting up guidelines and suggesting amendments to DCA to recognise and govern over-the-counter (OTC) drugs. Since risks and warnings are not required on container labels for consumers, absence thereof does not violate the provisions of DCA and has no impact on litigations directly involving the consumers. If, however, the requirements mentioned in DCA, such as the caution statements required to be displayed for drugs under different schedules as explained hereinabove, are not met, the aggrieved person, the drug inspector or a registered consumer association may initiate action against the manufacturer and seller for violation of provisions of DCA.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

The State Licensing Authority is responsible for issuing licences for life sciences manufacturers. Form 28 is required under DCA to apply for a manufacturing licence. Rule 76 DCA provides the information related to the issue of manufacturing licences. A few important requirements can be highlighted as follows:

- The manufacture will be conducted under the active direction and personal supervision of competent technical staff.
- The factory premises shall comply with the conditions prescribed in Schedule M and Schedule M III in respect of medical devices.
- The applicant shall provide adequate space, plant and equipment for any or all of the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M.

- The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out such tests of the strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X DCA including proper housing for animals used for the purposes of such tests, the testing unit being separate from the manufacturing unit and the head of the testing unit being independent of the head of the manufacturing unit.
- The applicant shall make adequate arrangements for the storage of drugs manufactured by him.
- The applicant shall, while applying for a licence to manufacture patent or proprietary medicines, furnish to the Licensing Authority evidence and data justifying that the patent or proprietary medicines:
  (i) contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful;
  (ii) are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in formulations, and under the conditions in which the formulations for administration and use are commended;
  (iii) are stable under the conditions of recommended storage;
  (iv) contain such ingredients and in such quantities for which there is therapeutic justification; and
  (v) have approval, in writing, in favour of the applicant to manufacture drug formulations falling under the purview of new drug.
- The licensee shall comply with the requirements of "Good Manufacturing Practices" as laid down in Schedule M.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

In February 2020, the Food and Drug Administration (FDA) and CDSCO came together to sign a Memorandum of Understanding (MOU) on the Safety of Medical Products. In 2015, the UK's Medicines and Healthcare products Regulatory Agency also signed an MOU with CDSCO, as part of plans to increase collaborations between the two countries to keep medicines and medical devices safe.

Before that, in 2014, FDA and CDSCO had come together and agreed to conduct a joint inspection and audit of pharmaceutical manufacturing companies in India. The agreement signed between FDA and CDSCO did not permit Indian regulators to inform pharmaceutical companies about the inspection plans beforehand. However, FDA was required to inform local regulators before undertaking inspections so that Indian inspectors could be there to observe the same.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

The impact of manufacturing requirements or violations thereof is that the violators are liable to penalty under DCA consisting of both imprisonment and a fine.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

There are various laws that govern mergers and acquisitions in India. The Acts that govern the same are described below:

- **The Companies Act, 2013 and the Companies (Compromises, Arrangements and Amalgamations) Rules, 2016** – Sections 230–233, 235–240, 270–288, etc. govern mergers and acquisitions, known as amalgamations, in India. When an arrangement is proposed for such scheme of merger, etc., a joint petition is required to be filed before the National Company Law Tribunal (NCLT) under Sections 230–232 specifying the purpose of the scheme.
- **The Competition Act, 2002** – This Act governs and regulates mergers and acquisitions of companies such that any arrangement that is anti-competitive, or is likely to have an appreciable adverse effect on competition in India, is prohibited.
- **The Securities and Exchange Board of India Act, 1992** – This Act regulates the securities markets in India and the mergers and acquisitions involving companies that are listed on stock exchanges in India. Apart from this Act, the regulations made thereunder, read together with circulars, guidelines, directions, orders and notifications issued by the Securities and Exchange Board of India constituted under this Act, govern such mergers and acquisitions.
- **The Foreign Exchange Management Act, 1999 (FEMA)** – FEMA, read together with the rules, regulations, circulars, orders and directions made thereunder, regulates foreign investment in India. It is necessary to ascertain the extent of foreign direct investment (FDI) allowed in specific sectors of industry and the limitations associated with such investments and amalgamation of companies. Currently, the medical devices sector is allowed 100% FDI through the automatic route, although it is governed under DCA. FDI in pharmaceuticals is allowed only up to 74% through the automatic route while big-ticket acquisitions are required to get additional clearance.
- **The Reserve Bank of India Act, 1934** – The orders, directions, regulations and notifications issued by the Reserve Bank of India (RBI) regulate sector-wise mergers and acquisitions. The investments allowed under the automatic route of FEMA do not require approval of the Government or RBI. However, investments marked for the Government route require approval from RBI.
- **The Income Tax Act, 1961** – This Act governs taxation-related aspects of mergers and acquisitions in India, such as cross-border transactions, double taxation avoidance, etc.
- **DCA** – This is the only Act that governs life sciences products in India. Any merger and acquisition in India in the sector of life sciences products is required to adhere to the provisions of this Act, especially relating to manufacturing, import, sale and labelling of life sciences products, amongst other considerations.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

Previously, the Indian Government did not allow a foreign company to acquire ownership of more than a 49% stake in India pharmaceutical companies. At present, however, 74% FDI in the pharmaceutical sector is allowed under the automatic route and thereafter through the Government approval route. For medical devices, 100% FDI is allowed through the automatic route.

The entity formed in India arising out of foreign ownership, as well as the foreign owner to some extent, is liable for injuries caused by use of a life sciences product or for non-compliance with the laws on FDI and mergers and acquisitions.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

The principal legislation and regulation governing the advertising, promotion and sale of drugs, medical devices and other life sciences products is the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (DMRA), which was enacted in 1954 with the object of controlling/prohibiting the advertisement of drugs and remedies that claim to possess magic qualities in certain cases. "Drug", "Magic Remedies" and "Advertisement" are key terms defined under DMRA. The term "Drug" is defined to include any medicine, substance, device or article that affects the organic structure of humans or animals, or any component of it. "Magic Remedy" is defined to include talismans, mantras, *kavacha*, and any other charm that is alleged to possess miraculous powers of diagnosing, curing, prevention, etc. of certain diseases. "Advertisement" under DMRA can be in any form, such as a notice, circular, wrapper, label, announcement (oral, smoke or light) or any other document. There is a general prohibition under DMRA of misleading and false advertisements.

Apart from the above, misleading advertisements are also governed under CPA. As mentioned above, advertisements in India are also regulated by ASCI and complaints made to ASCI are escalated to the Consumer Complaints Council under CPA, which may take necessary action against any misleading advertisement.

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off-label promotion")?

In India, there are no clear guidelines on the use of off-label drugs. However, prescribing off-label drugs and marketing the same by pharmaceutical companies are regarded as an offence under DMRA.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

In India, DMRA, CPA and ASCI curtail and restrict misleading advertisements with respect to drugs. A misleading advertisement has an impact on litigation concerning life sciences products if a consumer is directly aggrieved by such advertisement. Otherwise, such litigation arises only upon a complaint by ASCI or a consumer association.

As regards litigation under DCA, regulation of the advertising, promotion and sale of drugs and medical devices does not have a direct impact, although a misleading advertisement may invoke provisions of DCA if such advertisement falsely claims that a drug or medical device is approved or safe to use after having conducted clinical trials while no such trials have been conducted. In a recent case, Indian manufacturer Patanjali Ayurved claimed in its advertisements that its medicine "Coronil" was a cure for COVID-19, although no clinical trials were conducted. The Drug Department took cognisance and sought clarification, which resulted in the manufacturer removing all misleading advertisements and introducing Coronil as an Ayurvedic/herbal immunity booster instead.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with GDPR standards?

In India, life sciences companies that distribute their products globally are either of foreign ownership or of Indian ownership. Due to global businesses, Indian companies are required to comply with the EU's GDPR and subsidiaries of such Indian companies located in the EU automatically become liable under GDPR. Thus, life sciences companies, regardless of geographical location, mostly comply with GDPR standards and with other local data protection laws in the country where they are doing business.

However, Indian companies that do not have global presence or business do not have to comply with GDPR standards.

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

There is no legislation on the confidentiality of documents or information. Nonetheless, courts in India do recognise, and secure confidentiality of, documents produced in litigation. The restrictions on a company to maintain confidentiality of such documents in a litigation is to file such documents in a sealed cover and inform the court that the same are confidential documents. Whether such documents are confidential, or whether the company has itself not maintained confidentiality, could become a question of trial.

Confidential documents are managed in a litigation through Confidentiality Clubs in some jurisdictions. Confidentiality Clubs, which is an evolving concept, can be set up either by way of an agreement between the parties to the litigation or by an order of the court. Only those individuals who are members of the Confidentiality Club can access confidential documents.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

Digital Health in India refers to the tools and services used for health services with the help of information and communication technologies, including the prevention, diagnosis, treatment, monitoring and management of diseases. The MoHFW regulates this sector.

The Digital Health sector is continuously growing in India, and some of the key emerging technologies include: telemedicine; the Internet of Medical Things; robot-assisted surgery; self-monitoring healthcare devices; electronic health records; health service aggregation; mobile health; targeted advertising; e-pharmacies; cloud computing; and artificial intelligence.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

Clinical testing must be conducted in accordance with the protocol laid down by the Ethics Committee, the Drug Controller General of India (DCGI) and the Good Clinical Practice (GCP) standards, as well as in compliance with all other prevailing rules and regulations under DCA. For regulatory clinical trials, academic institutes should make sure that their Ethics Committee is registered with the Licensing Authority. It is mandatory for all clinical trials to be approved by the Institutional Ethics Committee (IEC). Registration of clinical trials with the Clinical Trials Registry – India (CTRI), which is hosted at ICMR's National Institute of Medical Statistics, is a free and online public record system for registration of clinical trials being conducted in India and was launched on 20 July 2007. Registration with CTRI for all regulatory clinical trials is now mandatory, as is written consent from all participants. It is also mandatory to report serious adverse events to DCGI and IEC.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

There is no direct jurisdiction under DCA or rules made thereunder that recognise liability for failure to test in certain patient populations. Currently, compensation relating to clinical trials is limited to harm and injury incurred during said trials. However, in case of any adverse reactions from a drug, a complaint can be made under DCA, which would be reported forthwith to the Licensing Authority. Please see Rule 28.1 Schedule M DCA.

In case any adverse effect is reported due to an approved drug or medical device, the aggrieved person or a consumer association can seek compensation under CPA, and a defence by the drug manufacturer that the drug or device was approved by DCGI can be countered by second-guessing the clinical trial. It is open to an aggrieved person to show that the drug company was negligent during the clinical trial or submitted incorrect data. The aggrieved person can also show that he belongs to a particular patient population and the drug company was negligent for failure to test in that population. This has, however, not yet undergone any judicial scrutiny.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

Yes. But only by way of a waiver in cases of extreme emergency, epidemics, etc. as well as when there is no available treatment for that disease.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

Waivers of liability are typically not utilised in India. Nonetheless, any agreement of waiver would be illegal as it would be contrary to the provisions of laws on drugs, medical devices, etc. in India.

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

Yes. GCP is a set of guidelines for biomedical studies that encompasses the design, conduct, termination, audit, analysis, reporting and documentation of studies involving human subjects. GCP conducts, designs and records trials on human subjects and its guidelines were set up by CDSCO. Under these guidelines, an Ethics Committee is formed that keeps a check on protocol, methods and other aspects necessary for conducting an ethical trial with regard to subjects in the trial. The fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well-being of the study subject. It aims to ensure that studies are scientifically and ethically sound and that clinical properties of pharmaceutical substances under investigation are properly documented. The guidelines seek to establish two cardinal principles: protection of the rights of human subjects; and authenticity of biomedical data generated.

ICMR provides guidelines for maintaining the standard for biomedical research and provides credibility to results of trials at both the national and global level.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

Recall is an action taken to withdraw/remove drugs from distribution or use, including corrective action for which deficiencies are reported in quality, efficacy or safety. In DCA, there are references for product recalls, complaints and adverse reactions.

In India, DCGI regulates pharmaceuticals and medical devices and is part of CDSCO, a regulatory body at a national level, both of which assure that drug products are rigorously tested for safety and efficacy before marketing. As per the World Health Organization, the prevalence of spurious, falsely labelled, falsified or counterfeit medicines that are deliberately and fraudulently produced, packaged and/or mislabelled is a growing trend worldwide. Drug recalls are conducted for seriously defective products that pose health risks to patients voluntarily by manufacturers or by mandate of regulatory authorities

Recall is classified by regulatory authorities to a particular product recall indicating a relative degree of health hazard:

- **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death and is banned under Section 26A DCA.
- **Class II** is situation in which the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III** is a situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences.

Recall is of two types: voluntary; and statutory. Voluntary recall is triggered by a manufacturer in response to an incident affecting the quality, safety and efficacy of a batch/product of drug. Statutory recall is carried out in response to direction or mandate from the regulatory authorities (Central/State) in situations that violate law, such as drugs that are Not of Standard Quality, banned drugs, or any violation of rules.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

In India, medical devices fall under the ambit of drugs. Under the Medical Devices (Amendment) Rules, 2020, which amended the existing Medical Device Rules, 2017, all medical devices in India are to be regulated as "drugs".

7.3 How do product recalls affect litigation and government action concerning the product?

If a manufacturer recalls its products, it does not make them automatically liable for any action. Evidence against said manufacturer is to be provided before a court of law to make them liable.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

Recalls in the United States or Europe may have a cascading effect and sometimes result in recalls in India as well. It depends on the reasons for recall and whether the products contravene any laws in India or continue to meet Indian requirements and standards; therefore, recalls in other jurisdictions may not result in a recall in India.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

The MoHFW has proposed a new bill, the Digital Information Security in Healthcare Act, 2018 (DISHA), to govern data security in the healthcare sector. The purpose of this Act will be to provide for electronic health data privacy, confidentiality, security and standardisation. The MoHFW, through the proposed DISHA, plans to set up a statutory body in the form of a national Digital Health Authority for promoting and adopting e-health standards, enforcing privacy and security measures for electronic health data, and regulating the storage and exchange of electronic health records. In addition, the Personal Data Protection Bill, 2019 was introduced in the Lok Sabha on 11 December 2019, which intends to provide for the protection of personal data of individuals, and establishes a Data Protection Authority for the same.

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

When a product is recalled by the manufacturers, a careful approach is required to ensure that the recall falls within the DCA framework.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

The law in India provides for class action suits under the Companies Act and the aggrieved party can approach the NCLT. However, this class action suit is in respect of members and depositors (both terms are defined under the Act) approaching the NCLT if they believe that the affairs of the company are being conducted in a manner detrimental to the interest of the company and its shareholders.

However, in case of personal injury/product injury, Indian laws do not recognise class action suits. There is, however, a procedure for "representative action" where a claimant or defendant can represent a group of individuals with the same interest in a single cause of action. In cases under CPA or DCA, consumer associations can represent several individuals in such "representative actions".

In circumstances where several similar litigations are pending before the same forum, all such cases can be combined with the consent of the parties in those cases and disposed of by a single order.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Personal injury/product liability claims can be brought as individual lawsuits or as representative lawsuits. As mentioned above, multiple individual lawsuits may also be heard and disposed of together with the consent of the parties.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

Product liability claims have been allowed under DCA. Section 27 DCA makes manufacturers, sellers and distributors liable for any contravention of DCA in respect of any drug, medical device, etc. governed by DCA.

Strict liability for defective products has been recognised under CPA, although the claimant is required to prove the damaged suffered due to the defective good.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

The Bar Council of India Rules do not permit lawyers to advertise in any way in India and lawyers can be prosecuted under the provisions of the Advocates Act, 1961.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

In India, there are no conditional free arrangements or damages-based arrangements. Lawyers typically provide services on a pre-determined fee structure independent of the outcome of the litigation.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

If a company is found liable in one case, it is considered *res judicata* only against the same parties and the same cause of action. If there is another claimant for the same product or service, the earlier case would not act as *res judicata*. Rather, if the earlier case relates to the same defect or negligence in the same product, it acts as a precedent and could be relied upon in the subsequent case.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

A company is required to comply with the provisions of DCA and the rules and regulations framed thereunder. Any non-compliance with said provisions gives rise to a cause of action against such company regardless of the steps taken by such company to improve their product later.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

Adverse events experienced by other product users are admissible in evidence to corroborate the claims of the plaintiff. These adverse events can be supported by way of expert evidence to assist the courts and even such other users can be called as witnesses.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

There are no "blocking" statutes in India that would prevent deposition based on jurisdiction. The company can produce witnesses voluntarily and at least one company witness is always required to prove the pleadings and other documents filed by the company. The witnesses can also depose and be cross-examined over video conferencing as provided under video conferencing rules in some jurisdictions. If the witness does not agree or is unable to appear in person in India from outside the jurisdiction, parties may opt to go through the Hague Convention to obtain testimony or depose through video conferencing.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

The attorney-client privilege in context of litigation is well recognised in India under Sections 126–130 of the Indian Evidence Act, 1872, the Advocates Act, 1961 and the Bar Council of India Rules. However, any communication between an attorney and his client for an illegal purpose, or in respect of any fact observed by the attorney showing that a fraud has been committed, is not covered.

Under the Bar Council of India Rules, an advocate licensed to practise before the courts cannot be a salaried employee. In other words, in-house counsel that are salaried employees are required to surrender their licences to practise. However, the attorney-client privilege is found to be applicable to such in-house counsel as well in view of several court decisions in India.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

Although attorney-client privilege is available in several common law countries, it is always advisable to mark or highlight all communications with counsel as "Privileged and Confidential". It is vital to understand and consider the laws on privilege protection of the relevant jurisdictions, and communication should always be in accordance with the limitations of the privilege protection. It is best to communicate via documents (email, letters, etc.) or to share documents with only those attorneys that are in jurisdictions where such privilege is recognised.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

There are no specific limitations on bringing suits against foreign defendants. It is necessary that the claims made by the defendant and cause of action fall within jurisdiction of the courts in India. India is also a signatory to the Hague Convention on the Service Abroad of Judicial and Extra-Judicial Documents in Civil or Commercial Matters, and declarations made by India in said Convention are applicable for suits against foreign defendants regarding service of documents, etc.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

The decision, technical evidence and other documents of U.S. litigation can be proved as fact in any "follow-on" litigation in India. However, the question of interpretation of documents and technical statements would be considered in light of Indian laws. Thus, U.S. litigation has very limited impact on litigation in India. Moreover, if direct and straightforward contravention of DCA or other laws of India is made out in any litigation in India, U.S. litigation would have much less impact and it would be tried and adjudicated based on Indian laws.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

The laws in India have emanated from UK laws and, even now, laws in India are more akin to UK laws than U.S. laws. Foreign decisions, including those rendered either by UK or U.S. courts, do not have a binding effect on Indian courts; however, they do have persuasive value. There is thus likelihood of litigation evolving as a result of U.S. litigation, provided that U.S. laws are not contrary to any law in India.

Manisha Singh is a founder and the Managing Partner of the firm. She oversees and supervises all practice groups at the firm. Manisha is known and respected for her deep expertise on prosecution and enforcement of all forms of IP rights and for strategising and managing global patents, trademarks and designs portfolios of large global and domestic companies. Her keen interest in using and deploying the latest technology tools and processes has immensely helped the firm to develop efficient IP service delivery models and to provide best-in-class services. She is also known for her sharp litigation and negotiation skills. She has been involved in and has successfully resolved various trademarks, copyright and design infringement and passing off cases in short timeframes and in the most cost-efficient manner, applying out-of-the-box strategies and thinking. She is a member of several international IP associations, such as AIPLA, AIPPI, APAA, ECTA, FICPI, INTA, LESI, and MARQUES, and actively participates in the committee works of these organisations.

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