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The Role of Contract Law in Shaping the Pharmaceutical Sector: A Legal Study

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Abstract

Any agreement which can be enforced by law is a contract. The law of contracts is crucial in pharmacy, regulating agreements between various stakeholders like pharmaceutical companies, suppliers, distributors, government entities and even patients. These contracts cover areas like supply agreements for raw materials and finished products, clinical trial agreements, licensing agreements for intellectual property, and more. Effective contract management ensures compliance, minimizes risk, and facilitates the smooth operation of the pharmaceutical industry. Business connections are established by every pharmaceutical company, with different manufacturers, suppliers, service providers, financial institutions, etc. In all these transactions, contracts are involved and regulatory authorities worldwide mandate for clearly defined, agreed and controlled contracted services. Various types of contracts, along with types of clauses required to be covered in such contracts, which are entered into by the pharmaceutical industry, with its various stakeholders, in India as well as outside, have been explored in this article. The application of Law of Contracts has been illustrated in the regulatory agencies of USA, European Union and India. Application of Law of contracts has been explored from the stage of inception to closing of a pharmaceutical company. The three types of contracts (Contracts by Agreement, Standard Form Contract and Promissory Estoppel) have been described, with cited case studies. Salient features, key types of agreements, key considerations, common examples, and specific applications in pharmaceutical industry, common clauses, of the three types of contracts have been described. The authors conclude that in view of the significant application of Law of Contracts in pharmaceutical industry, it would be prudent if the students / researchers in pharmacy, particularly those in the area of drug regulatory affairs, be fully aware of this law, and that this law may be included in the Pharmacy curriculum.

Keywords: Contracts; Standard forms contract; Promissory estoppels; Law of Contracts; Contracts by Agreement

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1. Introduction

Discovery, research, development, production, marketing and sale of pharmaceuticals, cosmetics, medical devices, etc. (referred to as drugs & pharmaceuticals) are the important functions of the pharmaceutical industry. As on date, the pharmaceutical industry is a multibillion-dollar industry, involving a multilayered, complex web of organizations, systems and products, which work together to achieve the above functions. Various stakeholders in pharmaceutical industry include manufacturers, distributers, sellers, medical professionals and consumers. All these stakeholders enter into a number of contracts on a day-to-day basis.

Today, India is ranked third globally in production of drugs & pharmaceuticals by volume and exports these to around 200 countries all over the world. Growth rate of pharmaceutical industry in India is 10 – 12 % and Indian pharmaceutical sector is projected to reach $ 100 billion, triggered by its strong and vibrant domestic manufacturing base. (1)

Pharmaceutical industry has developed into one of the strongest industrial sectors in the past century, which is catalyzed by rapid advancements in science and technology. Along with such growth, there also comes a need for a strong, vibrant legal system which would govern the large number and variety of transactions (contracts) that occur daily in pharmaceutical industry. Stakes in the contracts in pharmaceutical industry may be very high, and hence, pharmaceutical contracts need utmost level of care and caution in drafting of such contracts. Some important clauses, such as confidentiality, non-disclosure, IPRs handling, indemnity, etc., need to be drafted very precisely, keeping in mind the present goals of the stakeholders as well as any future contingencies which may arise subsequently.

Various types of contracts, along with types of clauses required to be covered in such contracts, which are entered into by the pharmaceutical industry, with its various stakeholders, in India as well as outside, have been explored in this article.

2. Law of contracts

An agreement which is enforceable by law is a Contract. There exist reciprocal promises between two or more parties, in an agreement. Each party would be legally

bound by the promise made by him, in case of a contract. (2)

The law of contracts is crucial in pharmacy, regulating agreements between various stakeholders like pharmaceutical companies, suppliers, distributors, government entities and even patients. These contracts cover areas like supply agreements for raw materials and finished products, clinical trial agreements, licensing agreements for intellectual property, and more. Effective contract management ensures compliance, minimizes risk, and facilitates the smooth operation of the pharmaceutical industry.

All pharmaceutical companies enter into a number of business connections (contracts) with a large number of manufacturers, suppliers, service providers, as well as regulatory authorities, worldwide. Regulatory authorities demand correctly defined, mutually agreed upon and controlled contracted services, within the ambit of law. The application of Law of Contracts shall be illustrated in the regulatory agencies of USA, European Union and India.

3. European Union

A written contract between the partners, which clearly define the duties and responsibilities of each party, are required as per the EU-GMP Guide and international regulations. (3)

The European Medicines Agency (EMA) operates under a framework of European Union (EU) law, including regulations and directives that harmonize contract law across member states. While the EMA itself doesn't have a separate "law of contracts," it is governed by general EU contract law principles, as well as its own specific procurement rules for contracting with external entities.

Here's a breakdown:

4. EU Contract Law:

4.1 Harmonization:

The EU has been working towards harmonizing contract law across member states through directives and regulations, aiming for a common set of legal principles.

a) Hard Law vs. Soft Law: This includes both "hard law" (binding regulations and directives) and "soft law" (principles or restatements of rules).

b) Principles of European Contract Law (PECL): The PECL, created by academics, offers a set of model rules based on common principles found in various EU legal systems, aiming for a uniform approach.

c) Determining Applicable Law: If the parties don't choose a governing law, the applicable law is often determined by the type of contract, such as the seller's country of residence for sales contracts or the property's location for real estate contracts.

4.2 EMA Procurement

a) Direct and Framework Contracts: The EMA utilizes both direct contracts (specifying deliverables and timelines) and framework contracts (establishing long-term relationships).

b) Framework Contract Types: Framework contracts can be single, cascade, or involve re-opening of competition, depending on the procurement structure.

c) Service Level Agreements (SLAs): The EMA negotiates and signs SLAs with contractors to define contract management procedures and quality standards.

d) Compliance: The EMA ensures compliance with legal obligations, including employment, tax, and social legislation, as well as obtaining necessary permits.

4.3 Contract Modifications:

a) Publication of Modifications: The EMA is required to publish lists of contract modifications, including those below certain financial thresholds.

b) Legal Basis: These modifications are governed by the EMA's Financial Regulation and are published on the agency's website.

4.4 General Principles:

a) Offer and Acceptance: A contract generally requires an offer from one party and acceptance by the other.

b) Consideration and Intent: Other essential elements include consideration (something of value exchanged) and the intention to create legal relations.

5. US FDA

In the context of the U.S. Food and Drug Administration (FDA), contract law governs agreements between parties, particularly in the area of drug manufacturing and other regulated activities. The FDA's role is to ensure the safety and effectiveness of regulated products, and this often involves contracts between manufacturers, suppliers, and other entities involved in the product lifecycle. These contracts outline responsibilities, quality standards, and compliance with FDA regulations.

Here's a breakdown of key aspects:

5.1 FDA Regulations and Contract Manufacturing:

a) Quality Agreements: The FDA guidance on contract manufacturing arrangements emphasizes the importance of quality agreements between owners (manufacturers of drug products) and contract facilities. These agreements define manufacturing activities, ensure compliance with Current Good Manufacturing Practice (CGMP) requirements, and clarify roles and responsibilities.

b) Contracting Officer's Authority: The FDA Contracting Officer (CO) is the sole authority for making changes to contracts, including those related to price, terms, and conditions. The CO is also the only individual authorized to obligate government funds and accept non-conforming work.

c) Representations and Warranties: FDA regulations may require contractual clauses where parties represent and warrant their compliance with FDA regulations and standards. This ensures that products and services meet regulatory requirements and minimizes legal and regulatory risks.

5.2 Key Contractual Elements in FDA-Regulated Industries:

a) Scope of Work: Contracts clearly define the specific services or products being provided, including deliverables, timelines, and performance standards.

b) Quality Standards: Contracts often incorporate quality standards, including CGMP regulations, to ensure the safety and efficacy of products.

c) Liability and Indemnification: Contracts may outline liability for product defects, breaches of contract, or non-compliance with regulations.

d) Inspection and Acceptance: Contracts specify procedures for inspection and acceptance of goods and services, including timelines and methods for addressing non-conformities.

e) Data and Information Sharing: Agreements may include provisions for sharing data and information between parties, such as inspection reports, compliance information, and research data.

5.3 Examples of Contractual Relationships:

a) Contract Manufacturing: Frequently, pharmaceutical companies outsource some manufacturing operations (in part or full) to a Contract Research Organization (CRO) or a Contract Development and Manufacturing Organization (CDMO). Contracts define the responsibilities of both the "owner" (the company that owns the product) and the "contracted facility" (the CMO/CDMO).

b) Clinical Trials: Clinical trial agreements define the responsibilities of sponsors, investigators, and research sites in conducting clinical trials for new drugs.

c) Supplier Agreements: Contracts with suppliers of raw materials, components, or packaging materials ensure that these materials meet FDA quality standards.

5.4 Importance of Legal Counsel:

Given the complexity of FDA regulations and the potential legal ramifications of non-compliance, it's crucial for parties involved in contracts regulated by the FDA to seek legal advice from experienced attorneys. In essence, contracts play a critical role in ensuring compliance with FDA regulations and maintaining the safety and effectiveness of products regulated by the agency. Understanding the key elements of contracts in this context is vital for all parties involved.

6. India – CDSCO:

In India, the Drugs and Cosmetics Act, 1940, and rules thereunder, 1945, govern the Central Drugs Standard Control Organization (CDSCO). Contracts within CDSCO, particularly those related to services and procurement, are guided by the Indian Contract Act, 1872, and specific terms and conditions outlined in tender documents and agreements.

6.1 Key Aspects of Contracts in CDSCO:

a) Governing Law: The Indian Contract Act, 1872, forms the foundation for contract law in India and is applicable to CDSCO contracts.

b) Types of Contracts: CDSCO utilizes various contracts, including those for services (e.g., housekeeping, data entry), procurement, and clinical trials.

c) Contract Formation: Contracts can be express (written or spoken) or implied (inferred from conduct).

d) Key Contractual Elements: CDSCO contracts typically include details on the scope of work, service level agreements (SLAs), payment terms, and termination clauses.

e) Specific Terms and Conditions: Service-specific terms and conditions (STC) and general terms and conditions (GTC) are often part of CDSCO contracts, with STC superseding GTC.

f) Tender Documents: Tender documents, including instructions to bidders, scope of work, and evaluation criteria, form an integral part of the contract formation process.

g) Monitoring and Compliance: CDSCO contracts often include provisions for monitoring mechanisms, compliance with standards (like GCP for clinical trials), and reporting requirements.

h) Dispute Resolution: Disputes related to annual contracts are typically under the jurisdiction of the Delhi High Court.

i) Penalties and Fines: Penalties may be imposed for breach of contract, faulty services, or delayed payments.

j) Transparency and Accountability: CDSCO aims to ensure transparency and accountability in its contractual processes.

k) Online Systems: CDSCO is increasingly implementing online systems for application, review, and processing of permissions/letters related to various activities.

Pharmaceutical companies develop, manufacture, distribute and market drugs & pharmaceuticals. These may also be licenced for trading in generics / branded medicines and medical devices. In all these products, a variety of rules and regulations may be applicable, including those of IPRs, and would involve contracts. (4)

To better understand the applications of Law of Contracts in pharmacy, we may have to trace out the origin of a drug / pharmaceutical device / medical device in a pharmaceutical industry, and the various stages through which it progresses, before it may be marketed. The journey continues when the products are marketed, until the products expire or are recalled.

7. Role of Contracts in the Lifecycle of a Company

7.1 Company formation

A company is a legal entity formed by a group of individuals to engage in business or trade with the intention of earning profits or achieving specific objectives. Companies exist as separate legal entities, meaning they are distinct from the people who own or manage them. The concept of a company plays a crucial role in modern commerce, offering a framework for businesses to operate, grow, and ensure legal compliance.

In this stage, a number of contracts are entered into, when individuals join together to form a company.

7.2 Procurement of finances

To start any business, including formation & running of a company, money is required. It is very rare that any individual / group of individuals can pool their personal finances, in order to start a company. In majority of the cases, once a company is formed, it would seek the finances through financial institutions, banks, general public (in the form of shares / debentures, etc), all of which involve entering into a number of contracts.

7.3 Hiring of manpower

Once the basic framework of a company is ready, a very important stage would involve hiring of various professionals (manpower), in the fields of finance, legal, technical, office, security, etc. Whenever any employee is recruited in a company, he has to sign a "contract" of employment, whether the employment is regular / adhoc / temporary, etc.

7.4 Building / construction of company office

Depending upon the type of company, a building / office would be constructed / hired. In all cases, a number of contracts would be required to be signed, say, with the civil engineers, government bodies, etc. Also, to procure water / electricity / gas connections, and for environmental clearance, some new contracts would be needed to be signed by the company.

7.5 Purchasing activity (raw materials, equipments, packaging materials, etc)

Depending upon the type of company, a company may need to purchase raw materials, equipments, packaging materials, etc. Even if a company is not involved in any manufacturing activity (say, it is a trading company only), the company would require to purchase office furniture, computers, air conditioners, etc. Besides, even a trading company would be requiring to enter in to a number of contracts, for buying & selling activities.

7.6 Governmental / legal obligations

In starting / running any company, a number of governmental / legal obligations may be required to be completed. This may involve obligations to meet environmental norms, legal obligations (such as ensuring compliance of Factories Act, Employees Provident Fund Act), seeking licences for pharmaceuticals (import / manufacturing / export / sale licences, etc) and so forth. All these activities / obligations again involve entering into a number of contractual obligations.

7.7 Import / Export / Manufacturing / Selling activity

Any company would be involved in import / export / manufacturing /selling, etc., whether its product is goods, or services or advice. All these activities would involve signing of contracts.

7.8 Day-to-day running of the company

Any kind of company would need to evolve certain rules & regulations, for its day-to-day activities. In case of pharmaceuticals, various kinds of proformas (such as manufacturing records, inspection records, analytical data, etc), needs to be prepared and preserved. All such activities involve delegation of responsibility and signing of various types of contracts.

7.9 Intellectual Property Rights

Frequently, a company would be generating an IPR, or would be working on a project, which involves an IPR not owned by the company. In such cases, the company would be signing different kinds of contracts.

7.10 Filing of INDs, NDA, ANDA, sNDA, etc

In pharmaceutical industry, filing of INDs, NDAs, ANDAs, sNDA, etc, is quite common. All such filings require extensive work, and filing of contracts.

7.11 Post marketing surveillance / Product recalls

When a new pharmaceutical product is launched, regulations require post marketing surveillance, frequently for a period of four years. A good company may keep on collecting post marketing surveillance data for the full product life, and all such activities require filing of contracts. Sometimes, a product needs to be recalled (as part of the regulatory compliance), which also involves filing of contracts.

7.12 Product advertising

All companies need advertisements, and may also need to comply with some laws on advertisements. In all advertising activities, contracts need to be signed.

7.13 Winding up of a company

Whenever a company is winded up or amalgated or merged in to some other company, interests of financial institutions / banks / shareholders, etc. need to be taken care of. In most cases, there would a prescribed procedure for the winding up of a company, and also for the transfer of various rights (such as transfer of marketing authorisation). All such activities would involve signing of a number of contracts.

Thus, it becomes clear that a large number and types of contracts would need to be entered into by any company, from the stage of its conception, day to day working and even when a company is wounded up.

8. Types of Contracts:

Following types of contracts are recognised in law:

8.1 Contract by agreement

8.2 Standard form contract

8.3 Promissory Estoppel

A brief description of these types of contracts, along with their applications in pharmaceutical industry, is given below.

8.1 Contract by agreement:

This is most common way of entering into a contract, wherein two or more parties sit together (physically or online) and enter into negotiations. When one party makes an offer and the other party accepts the offer, a contract would arise, which may be enforceable by law.

Essential features of Contracts by Agreement are:

- Both the parties are free to participate / negotiate and draw upon the various terms & conditions, to their mutual satisfaction.
- In these contracts, Courts would generally believe that both the parties are at equal footing, and there would hardly be any chance of dominance by one party (e.g., in a contract between an employer, say a large multinational firm and an employee, the Court would generally believe that the employee would be underprivileged and the firm may be in a dominating position).
- Once the terms and conditions of the contract have been settled by the parties, these are enforceable by law. However, both the parties may alter the terms & conditions, by mutual negotiations.

In the pharmaceutical industry, contracts by agreement govern various relationships, including manufacturing, licensing, supply, and research and development. These agreements ensure that all parties understand their obligations, quality standards, and potential liabilities.

9. Key types of agreements in pharmaceutical industry:

9.1 Manufacturing Agreements:

Purpose: These contracts outline the terms between a pharmaceutical company and a contract manufacturer for producing drugs or their components.

Key Elements: Product specifications, quality standards (including GMP), intellectual property rights, confidentiality, payment terms and manufacturing processes are typically defined.

Example: A company might outsource the production of a specific drug to a CMO (Contract Manufacturing Organization).

9.2 Licensing Agreements:

Purpose: These agreements allow a company to produce and sell a drug or technology that is owned by another company, in the form of patents, trademarks or technology.

Key Elements: Scope, Royalty payments, milestone payments, Remuneration, territorial rights, and duration of the license are specified.

Example: A smaller biotech company might license its novel drug to a larger pharmaceutical company for commercialization.

9.3 Product Supply Agreements:

Purpose: These contracts govern the supply of pharmaceutical products from a supplier to a purchaser, such as a distributor or retailer, or directly to health care providers. These agreements ensure that products reach the market efficiently and comply with regulatory requirements.

Key Elements: Product specifications, territory, logistics, delivery schedules, pricing, and payment terms are defined.

Example: A wholesaler might have an agreement with a manufacturer to purchase a certain quantity of a drug at a specific price.

9.4 Research and Development (R&D) Agreements:

Purpose: These agreements facilitate collaboration between companies, academic institutions and research organizations, on the research and development of new drugs and therapies.

Key Elements: Roles and responsibilities, Scope, funding, deliverables, confidentiality, data sharing, intellectual property rights, and milestones are outlined.

Example: Two companies might partner to develop a new cancer treatment.

9.5 Quality Agreements:

Purpose: These agreements define the quality standards and responsibilities of each party in a contract manufacturing arrangement.

Key Elements: GMP compliance, quality control procedures, and responsibilities for ensuring product quality are specified.

Example: A quality agreement between a pharmaceutical company and a CMO would detail how they will both ensure the drug is manufactured to the required quality standards.

9.6 Service Level Agreements (SLAs):

Purpose: These agreements outline the level of service a provider will deliver to a client, including timelines, performance metrics, and penalties for failing to meet the agreed-upon standards.

Key Elements: Specific services provided, performance indicators, reporting requirements, and dispute resolution mechanisms.

Example: A pharmacovigilance service provider might have an SLA with a pharmaceutical company outlining the timelines for reporting adverse drug events.

9.7 Technology Transfer Agreements:

Purpose: The Technology Transfer Agreements are meant to facilitate contracts involving transfer of technology or know-how, from one party to another, often in case of contract manufacturing.

Key Elements: Details of the technology, training requirements, and support obligations.

Example: A company transferring a manufacturing process to a CMO would use a technology transfer agreement to ensure the process is accurately replicated.

9.8 Credit Agreements:

Purpose: Frequently, a pharmaceutical company may borrow capital from an investment from a financial institution. This involves contracts covering the credit agreements, which outline the terms & conditions of the loan / finance.

Key Elements: Loan amount, interest rate, repayment schedule, and collateral.

Example: A pharmaceutical company might secure funding from a venture capital firm to support its R&D efforts.

9.9 Joint Venture Agreements

Joint venture agreements are strategic partnerships between two or more companies to share resources, knowledge, and risks in a particular project. In the pharmaceutical industry, these agreements are often used for drug development, manufacturing, and marketing.

Key Elements: Objectives: Goals and purpose of the joint venture.

Contributions: Resources and capital each party will contribute.

Management Structure: Governance and decision-making processes.

Profit Sharing: Distribution of profits and losses.

Duration: The lifespan of the joint venture.

9.10 Supply Agreements

Supply agreements are contracts between pharmaceutical companies and suppliers of raw materials, active pharmaceutical ingredients (APIs), or packaging materials. These agreements ensure a steady supply of high-quality materials necessary for drug production.

Product Specifications: Detailed descriptions of the materials to be supplied.

Quality Standards: Compliance with GMP and other regulatory standards.

Pricing and Payment Terms: Cost of materials and payment schedules.

Delivery Terms: Logistics and delivery timelines.

Contingency Plans: Measures for handling supply disruptions.

9.11 Clinical Trial Agreements

Clinical trials are required to test the safety and efficacy of new drugs. Frequently, a pharmaceutical company may decide (contracts) with some Clinical Research Organizations (CROs) or medical institutions, for the smooth conduct of clinical trials. Herein, Clinical Trial Agreements would govern the conduct of clinical trials.

Key Elements:

Study Design: Detailed plan of the clinical trial.

Regulatory Compliance: Adherence to ethical guidelines and regulatory requirements.

Funding: Financial terms for conducting the trial.

Data Management: Handling and ownership of trial data.

Publication Rights: Rights to publish the results of the trial.

9.12 Marketing and Promotion Agreements

Marketing and promotion agreements outline the terms for promoting and selling pharmaceutical products. These agreements can involve partnerships with marketing agencies, healthcare providers, or other pharmaceutical companies.

Key Elements:

Marketing Strategies: Detailed marketing and promotional plans.

Roles and Responsibilities: Duties of each party in the promotion.

Compensation: Payment terms for marketing services.

Compliance: Adherence to advertising regulations and industry standards.

Performance Metrics: Criteria for evaluating the success of marketing efforts. (5)

10. Key Considerations in Pharmaceutical Contracts:

10.1 Regulatory Compliance:

All agreements must comply with relevant regulations, such as GMP and data privacy regulations.

10.2 Intellectual Property:

Protecting intellectual property rights is crucial in the pharmaceutical industry, and contracts must address ownership, licensing, and confidentiality.

10.3 Data Security:

Pharmaceutical companies share information (commercial secrets, patient data, trade secrets, etc) with several partners (CROs, traders, regulators, financial institutions, etc), for which data protection measures need to be evolved, as part of the contracts.

10.4 Dispute Resolution:

Contracts should include mechanisms for resolving disputes, such as arbitration or mediation.

11. Standard Forms Contracts

Frequently, a company may deal with a large number of persons (buyers, sellers, shareholders, employees, etc), wherein signing of contract with each person individually, preceded by negotiations, may not be prudent and would be very time consuming. In such cases, the company may evolve some specific formats (of contracts), which would be presented to the other party (buyers, sellers, shareholders, employees, etc). Most of the terms & conditions of the contract would already be printed in the Standard Form Contract and the other party would be filling some information (name, legal status, etc) in the "dotted lines".

Such "Standard Form Contracts" are very common, whenever a company (or an individual) enters into a contract with, say, Railways (for booking of tickets), Insurance (buying an insurance policy), Banks (all kinds of financial transactions), etc.

In such contracts, usually one party would have drafted the conditions on its own, and very little choice is offered to the second party, entering into the contract.

Such contracts are legally admissible, although courts would very frequently analyse them to verify if any one party is wronged (or is in a negotiating position). (6)

Standard Form Contracts have no room for negotiations. Usually, the customer is not in a position to re-negotiate the standard terms of the contract, and even when he asks for it, the company's representative (e.g., bank or insurance company official) would have no authority to do so. In such contracts, the customer meekly accepts the contract; in a way, these contracts are imposed upon the customer compulsorily, if the customer wants to enjoy the services offered. These contracts are often termed as "take it or leave it" or "Compulsory Contracts".

Large business organizations (e.g., Railways, Banks, Insurance Companies, etc) may not be able to enter into separate contract with every individual (they are dealing with). Therefore, they keep printed forms of contract (i.e., SFC's) containing a large number of terms and conditions in "fine-print" which restricts and often excludes the liability of the other party under the contract. Briefly, one can say that the SFC's have arisen as a result of following factors:

a) Printed forms are convenient, in that they save time & efforts;

b) Usually in SFC's, one party stands in a dominating position (e.g., banks, railways, insurance companies, etc) where such party would pre-draft the terms & conditions, which would be imposed upon the second party (the customer). The customer is in no position to re-negotiate. The terms & conditions of such bargains would be already printed, and the company simply expects the customer to come forward and enter into such contracts. In majority of the bargains (say, between a customer and a bank or railways or insurance company), the customer is quite willing to enter into a contract.

12. Reasons for Acceptance of Standard Form Contracts:

Some of the reasons why SFC's are accepted by the customers, are enlisted below:

a) The terms & conditions in a SFC may involve legal jargon, and the customer may find it difficult to comprehend the same; he may consider it irrelevant too. To read these, lot of time needs to be spent, and the customer may also find that the company's representative is not in a position to alter the fine prints

b) In several SFC's, the company may not give full terms & conditions and may inform the customer to refer to some other document (in a different location). For example, the full description of a warranty of a mobile being sold in a sealed box, would be inside the box, and the customer can have access to it only after acceptance of the contract (i.e., only after purchase of the contract). Similarly, while purchasing a railway ticket, the full terms & conditions would be printed on the railway ticket (which is accessible to the customer only after he has purchased the same). Thus, the customer accepts the terms & conditions of SFC's notionally, by purchasing the goods.

c) The most important terms & conditions of the SFC's may not be prominent or bold, while the customer may be interested in the price and quality of the goods only. Hence, other than the price and quality, other terms & conditions may not be actually read by the customer, before the purchase.

d) Usually, the SFC's would be advertised or their main details would be explained briefly before the deal. Now the customer would be under social pressure to sign the deal (e.g., in a bank, while opening an account). Sometimes, the customer is in a queue (e.g., purchasing a railway ticket) and persons in queque after him would frown if the customer spends more time in reading the terms & conditions; he is under a pressure to sign the deal quickly. Sometimes, the company's representative would simply state: "Oh, these are legal formalities".

e) Usually, in SFC's, there exist unequal power positions. The customer is at a receiving end, with little or no power (either accept the deal or leave it) while the company is in a dominating position (having pre-drafted the terms & conditions, with little or no room for re-negotiations with the customer). Examples include medical or health insurance, vehicle insurance, rental agreements, banking transactions, etc. Thus, the customer may have no choice but to buy the commodity.

Common examples of such contracts include:

- Contracts with insurance companies
- Tenders
- Booking of railway/ air tickets
- Financial transactions (e.g., opening a bank account, getting a loan sanctioned, etc)
- Admission forms (say, in a college)

Standard form contracts are acceptable by courts, so long as these contracts do not encroach upon the rights of any one party. Usually, in these contracts, one party (say, Banks), will be pre-drafted the contract terms & conditions, while the other party (say, a customer wishing to hire a bank locker) would be required to sign on the dotted lines. Here, the second party (e.g., customer) usually has no say in drafting /altering the terms & conditions, and the first party (e.g., the banks) will have a dominating position. In majority of the cases involving standard forms contracts, the courts will usually look upon with suspicion, and ensure that the first party is not abusing its dominating position, while the second party has no choice (but to sign the agreement, upon the dotted lines).

Standard form contracts, while generally valid and legally binding in the pharmaceutical industry, can be subject to scrutiny regarding unfair or unconscionable terms. Courts may refuse to enforce clauses or entire contracts if they are found to lack meaningful choice for the adhering party or if they are deemed unfair.

Some considerations in checking the validity of Standard Forms Contracts are as follows:

a) General Enforceability: Standard form contracts, also known as "contracts of adhesion," are generally considered

valid under contract law, especially when used for efficiency in commercial transactions.

b) Indian Context: In India, standard form contracts are governed by the Indian Contract Act of 1872, with no distinction made between them and traditional contracts.

c) Potential for Unfairness: The primary concern with standard form contracts is the potential for unfair or unconscionable terms, particularly when one party has significantly less bargaining power.

Factors Affecting Validity of Standard Forms Contracts are as follows:

d) Lack of Meaningful Choice: If the adhering party had no real opportunity to negotiate or modify the terms, a court may find the contract or specific clauses unenforceable.

e) Unfair or Unconscionable Terms: Clauses that impose exorbitant fines, biased arbitration rules, or violate legal principles can be deemed invalid.

f) Consumer Protection Laws: Laws like the Consumer Protection Act, 2019 in India, provide additional safeguards for consumers who enter into standard form contracts.

g) Misrepresentation, Fraud, or Coercion: If the contract was entered into through fraud, misrepresentation, or coercion, it can be invalidated.

h) Ambiguity: Ambiguities in standard form contracts are generally resolved against the party who drafted the contract (contra proferentem).

Some Pharmaceutical Industry Specific factors include:

a) Regulatory Compliance: Pharmaceutical companies must ensure their standard form contracts comply with relevant regulations, such as those related to GMP (Good Manufacturing Practices) and other applicable requirements.

b) Specific Clauses: Contracts in the pharmaceutical industry may include clauses related to raw material sourcing, manufacturing, quality control, and intellectual property rights.

c) Transparency and Fairness: While standard form contracts can be efficient, pharmaceutical companies should aim for transparency and fairness in their terms to avoid potential legal challenges.

In essence, while standard form contracts are a practical tool for the pharmaceutical industry, parties should be mindful of potential legal challenges related to unfair or unconscionable terms and ensure compliance with relevant regulations.

13. Promissory Estoppel

Sometimes, there exists no formal contract (Contract by Agreement or Standard Forms Contract). Here, one party may make a promise to the second party, wherein the second party acts upon the promise made, the party making the promise becomes bound thereby, due to the application of "Law of Estoppel", in such a case. This is also applicable against the government. For example, in a hypothetical case, a government issues an order, whereby new small-scale units are invited to set up their industry in the state, with the promise that such new industries would not be subjected to sales tax (or some other tax), for a particular period (say, five years). Acting upon the promise, a new industry is set up. Now, if the government issues another order, after three years, that the sales tax exemption is withdrawn, this would attract the "Law of Promissory Estoppel", and the government would be barred from applying the new order to the new industries already set up.

Promissory Estoppel is widely applicable in pharmaceutical industry. (7, 8)

Promissory estoppel can be applied in the pharmaceutical industry when a company relies on a promise made by another party (including the government or another company) and suffers a loss as a result of that reliance when the promise is broken. This doctrine prevents the promisor from rescinding back if the promisee has taken some action and that the promisee would suffer a loss if the promisor goes back on his promise.

14.1 Application of promissory estoppel in the pharmaceutical industry:

14.1.1 Government Incentives and Regulations:

Scenario: A pharmaceutical company invests heavily in a new facility based on a government's promise of tax breaks or subsidies.

Application: If the government later revokes the incentive, the company can potentially invoke promissory estoppel to argue that it relied on the promise and should be compensated for the losses incurred due to the change in policy.

Example: In a case involving Hero Motocorp and Sun Pharma, they argued for 100% budgetary support based on a pre-existing exemption, which the government later rescinded. In this case, the Supreme Court observed that the doctrine of promissory estoppel would not apply against the exercise of legislative powers of the State.In this case, the High Court of Delhi, dismissed writ petitions filed by Hero Motocorp and Sun Pharma Laboratories Ltd. who claimed 100% budgetary support in lieu of the pre-existing 100% outright excise duty exemption for ten years from the date of inception. (9)

14.1.2 Agreements with Suppliers or Distributors:

Scenario: A pharmaceutical company relies on a long-term supply agreement with a crucial supplier, based on a promise of consistent pricing or delivery schedule.

Application: If the supplier suddenly changes the terms of the agreement, the pharmaceutical company can potentially seek damages under promissory estoppel if they can demonstrate they relied on the original promise to their detriment.

14.1.3 Research and Development Agreements:

Scenario: A pharmaceutical company collaborates with a research institution based on a promise of exclusive rights to the research findings.

Application: If the research institution later reneges on the agreement and grants rights to another party, the pharmaceutical company could potentially use promissory estoppel to protect its interests, especially if it has invested significant resources in the research.

14.1.4 Marketing and Advertising Promises:

Scenario: A pharmaceutical company launches a new drug based on a marketing campaign that promises specific outcomes or benefits.

Application: If the company later finds that the drug doesn't deliver on those promises and the marketing campaign is misleading, they could potentially face legal action from consumers or face regulatory penalties. Promissory estoppel could be relevant if the company relied on a promise from a third party (e.g., a marketing agency) regarding the accuracy of the campaign.

14.2 Key Elements of Promissory Estoppel in the Pharmaceutical Industry:

- **A clear and definite promise:** The promise must be clear, unambiguous, and not vague or uncertain.
- **Reliance:** The pharmaceutical company must have reasonably relied on the promise.
- **Detriment:** The company must have suffered a loss or detriment as a result of relying on the promise.
- **Injustice:** It must be unjust or inequitable to allow the promisor to go back on their promise.

14.3 Important Considerations:

- Promissory estoppel is often used as a shield to defend against a claim rather than a sword to initiate a claim according to Drishti Judiciary.
- Promissory estoppel may not be applicable if the promise is against public policy or law.
- Courts often balance the principle of promissory estoppel against the public interest.
- The specific facts and circumstances of each case are crucial in determining whether promissory estoppel applies

Promissory estoppel, a legal doctrine, could potentially apply in the pharmaceutical industry in scenarios where promises made by companies, particularly those related to future actions or benefits, are relied upon by stakeholders (like investors, employees, or customers) and these stakeholders suffer detriment due to the company's failure to fulfil the promise. The key is that the promise must be made with the intention of inducing reliance, and the promisee must reasonably rely on it, suffering a detriment as a result of the promisor's failure to act.

14.4 Promissory Estoppel and Its Relevance to Pharmaceutical Promises

Here's how it might apply in the pharmaceutical industry:

a) Promises about clinical trials and drug development: Pharmaceutical companies often make promises about the timeline or success of clinical trials or the development of new drugs. If a company makes a promise about a specific timeline for a trial or the expected outcome of a study, and stakeholders rely on that promise to make investment decisions or other actions, the doctrine of promissory estoppel could be invoked if the promise is not kept.

b) Promises about future pricing or product launches: Companies may make promises about future pricing policies or the launch of new products, and these promises could be relied upon by patients, hospitals, or distributors. If the company fails to keep these promises, and the promisee suffers a detriment (e.g., a loss of revenue for a distributor or increased healthcare costs for patients), promissory estoppel could be a legal avenue for redress.

c) Promises about employment or compensation: Like any other industry, pharmaceutical companies could face promissory estoppel claims related to promises made to employees about job security, bonuses, or retirement benefits.

d) Promises related to regulatory approvals: If a company promises that a drug will be approved by a certain regulatory body and investors rely on that promise to make investments, and the approval doesn't materialize, promissory estoppel could be used as a basis for a claim.

14.5 Key Considerations:

a) Clear and unequivocal promise: The promise must be clear and unambiguous, and the promisor must have known or reasonably foreseen that the promisee would rely on it.

b) Reasonable reliance: The promisee must have reasonably relied on the promise, and the reliance must be to their detriment.

c) Injustice: A court is likely to apply promissory estoppel only if it would be unjust to allow the promisor to go back on their promise.

d) No consideration: Promissory estoppel can apply even if there is no formal contract or consideration (something of value exchanged for the promise).

Example: Imagine a pharmaceutical company publicly announces that they are close to completing a clinical trial for a promising new drug for a rare disease. Investors, based on this announcement, invest heavily in the company. However, the clinical trial fails, and the drug is never developed. The investors could argue that the company made a promise to complete the trial successfully, they relied on this promise to invest, and they suffered a significant financial loss as a result of the company's failure to keep the promise. This scenario could potentially be grounds for a promissory estoppel claim

Promissory estoppel may not be applicable if the promise is against public policy or law.

Courts often balance the principle of promissory estoppel against the public interest.

The specific facts and circumstances of each case are crucial in determining whether promissory estoppel applies'

Promissory estoppel, a legal doctrine, could potentially apply in the pharmaceutical industry in scenarios where promises made by companies, particularly those related to future actions or benefits, are relied upon by stakeholders (like investors, employees, or customers) and these stakeholders suffer detriment due to the company's failure to fulfil the promise. The key is that the promise must be made with the intention of inducing reliance, and the promisee must reasonably rely on it, suffering a detriment as a result of the promisor's failure to act.

In Motilal Padampat Sugar Mills v State of Uttar Pradesh & Others, the Chief Secretary of the government issued an assurance that a total tax exemption would be available to a new industry, for a period of 3 years. On the basis of this assurance, M. P. Sugar Mills took huge loans and started hydro generation plant. However, afterwards, the government changed the tax policy, stating that the industries will be taxed at a varying rate. In this case, The Supreme Court applied the Doctrine of Promissory Estoppel and noted that relying on the government's assurance, the appellant took a huge loan. As the promise was made by the government and the company acted on the same (to its detriment), no tax should be imposed for a period of 3 years from the date of production (as promised by the government). (10)

In the case of "Dentro Pharmaceuticals (P) Limited vs The State of Tamil Nadu and Anr." on 29th Sept 1994, Madras High Court, it was held that it is not possible to hold that there is any scope for applying promissory stopped in the present case. (11)

15. Types of Pharmaceutical Contracts

The pharmaceutical industry is governed by a complex web of agreements that ensure collaboration, compliance, and efficiency across various operations. From manufacturing and licensing to distribution and research, each type of agreement plays a crucial role in the industry's success. Indian pharmaceutical companies, including pharma manufacturers, pharmaceutical formulation companies, utilize these agreements to navigate the competitive landscape and drive innovation.

In a rapidly evolving industry, understanding and effectively managing these agreements is essential for any pharmaceutical company aiming to achieve sustained growth and market leadership.

Some of the basic types of Contracts that may be entered into in the Pharmaceutical Industry include:

a) **Equipment and R&D Licensing:** These involve Contracts wherein an interested party contracts to obtain the use of certain Equipment from a Company in possession thereof. Such Equipment may include various tools, implements and machinery that are used in the manufacture and production of Pharmaceutical Drugs. Additionally, Research and Development is one of the primary areas of focus for any Pharmaceutical Company, as it leads to new innovations and products based on emerging knowledge and technology. Licensing allows companies to access knowledge and technologies developed outside their organizational boundaries.2 In recent times, Companies have begun to license such R&D from other well establish Pharmaceutical Companies in order to cut down on expenses and also benefit from the extensive resources possessed by the Licensors.

b) **Intellectual Property Licensing:** This is an agreement between holders of certain IP Rights including Patents, Trademarks, Designs and Copyrights, and third parties who wish to use such IPs for a limited period of time. Such third parties, called licensees, obtain the License from the IP holders, termed Licensors, for a specified period and a certain geographical area. In Pharmaceutical Contracts, such IP may include Trademarks for medicine brands, patented formula, Manufacturing Equipment Designs and Methods of Production among others.

c) **Outcomes Based Contracts:** These are value-based contracts which tie actual patient health outcomes to drug reimbursement and provide blueprints to payers for cutting costs of prescription drugs through proactive management of chronic patients. Value based contracts are those which provide the option of lowering prices of pharmaceuticals whilst improving outcomes for patients, thus ensuring that the consumers receive the greatest amount of benefit through the medicines they purchase. Along with Cost Cap Contracts and Indication Based Management Contracts, these are generally entered into by CDMOs whilst providing various pharmaceutical related services.

d) **Cost Cap Contracts:** These contracts come into the picture when a new pharmaceutical enters the market at a higher price than similar drugs. In such cases, the pharmacies negotiate a maximum per member per month cost of a drug with the manufacturers, which promotes market competition and lowers costs of prescription drugs.

e) **Indication Based Management**: This includes agreements where the price of a drug may be tailored to a specific medical condition (indication) for which its use is intended. This is quite different from uniform pricing, where the drug would be priced the same regardless of the condition. Here, the price of a drug reflects its potential benefits or value in a specific condition. For example, a drug may be priced higher for a life-threatening disease (indication) than for a less severe condition. This strategy helps the companies to manage health care costs, promotes innovation and ensures patient access.

f) **Lease Deeds:** These contracts are between the Lessor (owners) and the Lessee (users), which may involve immovable properties (such as a factory or warehouse) or for other items (such as specific machinery or equipment, or even services as part of the consideration). Thus, the Lessee may be expected to perform certain maintenance tasks on the property for the Lessor.

g) **Collaboration and Joint Venture Agreements:** Many a times, two or more individuals (or companies) may pool up their resources or expertise and enter into collaboration and / or joint venture agreements, to

achieve a specific target (for example, a research project or launching of a new drug). The specific roles and responsibilities of each participant would need to be defined clearly in the agreement. The participants may share the profits, losses or other costs involved in the venture. Such agreements are quite frequent even for entry into a foreign market, wherein two or more companies would save the costs / resources / time, etc.

h) Invention Assignment Agreements: Frequently, in research-oriented organizations, employees or researchers may be involved in high –value research, producing some patents / inventions (or other IPRs). Here, the company would need to enter into a contract with the researcher, at the time of recruitment itself, wherein the researcher would:

- disclose any prior patents / inventions (or IPRs) already in his possession, before joining the present assignment.
- fully disclose the requisite details for any patented work / invention (or IPRs) which he may create, over the course of his employment with the new company.

i) Credit Agreements: Frequently, a pharmaceutical company would require some loans (or investments) from financial institutions (e.g., banks) for the purpose of, say, funding a new project, or launch of a new drug. Such agreements between the lender (e.g., banks) and the borrower (e.g., pharmaceutical company) would outline the terms & conditions of the loan agreement (for example, for which specific purpose the loan amount may be utilized).

j) Quality Agreements: It may be difficult a pharmaceutical company to execute all steps / operations involved in a particular project, and the company may look towards a Contract Research Organization or Contract Manufacturing Organization. Herein, the contracts would specifically include certain quality benchmarks which need to be achieved, for the execution of the projects. In case the CRO or CMO fails to achieve the quality benchmarks, it may result in non-fulfilment of the agreement and result in financial or other implications for the CRO or CMO. The quality benchmarks may include safety, purity, potency of a product, or a specific time frame in which the project needs to be completed.

k) Product Supply Agreements: These contracts are very common in pharmaceutical industry, wherein a company may purchase some bulk drug, excipients, packaging materials, machinery spare parts, etc, as products. Here, the contract terms & conditions may specify the time line, product quality, minimum quantity required, inspection of goods, and contingencies for failure of supply or failure in quality of the products.

l) Technology Transfer Agreement: In the present scenario, many companies would look forward to use of technology, inventions, products or IPRs (trademarks, patents, etc) belonging to some other company. This may be required for launch of new products, as well as to reduction of manufacturing / research costs or improvements in company's products value. Herein the technology or product transfer may be achieved by way of assignment or licensing.

15.1 Common Clauses found in the above types of Contracts include:

a) Third Party Licensing & IP Rights: Intellectual Property Rights may include rights such as Trademarks, Patents, Designs and Copyrights. Pharmaceutical Companies often enter into IP licensing contracts with 3rd parties in order to gain monetary benefits from their IP Ownership. A 3rd party licensing & IP rights clause includes a requirement for the parties to the contract to give written notice to the other, in case of an infringement of either party's IP Rights by a third party. This may include impediments on the use of the parties' licensed technology, joint patent rights & inventions, or on the manufacture, use, sale, distribution, marketing, etc. of their products. The parties may also agree on a joint course of action to be taken in such cases.

b) Clauses of Confidentiality & Non-Disclosure: This clause imposes an obligation on the parties or certain persons within their organization to refrain from disclosing sensitive information pertaining to various aspects of the organization to the public or any third party. It also lists the various terms and conditions of such non-disclosure, permitted disclosures and contingencies therein. These Clauses are commonly used in the competitive pharmaceutical industry whose work involves an abundance of sensitive information including formulations, methods of production and so forth.

c) Representations & Warranties: The Representation and Warranties clause are primary boilerplate clauses of almost all commercial contracts including Pharmaceutical Contracts. This clause includes various statements of facts, or representations, made by one party to another, which induces the second party into entering the contract. Warranties, on the other hand, are promises made by one party to another that a condition or fact asserted is true and are backed by implied promises of indemnification in the event of such assertions being false. These clauses are also used for the purposes of allowing the contractor from disclosing information and avoiding future liability, promoting good faith, and allocating risk between parties.

d) Trademark Clause: Trademarks serve to identify and distinguish the source of goods or services of one party from those of others. Essentially, it serves as a brand identifier which helps consumers to recognize and select products or services. Trademarks are a form of IPRs. Thus, trademarks can be shared / leased / licensed / sold / transferred, etc., from one company to another, as a property. In all such transactions, agreements or contracts protecting trademarks, or allowing their use, need to be specified. Sometimes, one company is selling the product manufactured by

another company; here also, trademark clause needs to be specified.

e) **Indemnity Clause:** This is a contractual provision, wherein one party (the indemnifier) agrees to protect another party (the indemnitee) from some particular financial or legal liabilities (including financial losses, costs, expenses, damages or other implications). Thus, it shifts the risks of some potential losses, from the indemnitee to the indemnifier. Such clauses are essential in pharmaceutical contracts to manage the inherent risks involved in drug development, manufacturing, marketing, etc., of drugs and pharmaceuticals.

f) **Term & Termination:** Any contract must specify the term of the contract, after which the contract would expire. Generally, all contracts may also include a Termination Clause, which enlists certain conditions in which the contract may be terminated by either party. Such conditions may include failure to fulfill the contractual obligation (for example, failure to supply goods in time, or failure to supply goods of requisite quality).

g) **Fee for Service & Delay Policies:** In the "fees for service" contracts, a doctor is paid for each individual service he provides, such as consolations, tests, or procedures. Under these agreements, the doctor would charge fees from a third-party payer (for example, from an insurance company, government, or patients' employer company). Such contracts are quite frequent, for providing medical services to employees (say, in a large pharmaceutical company), or for government servants, or private individuals covered by a health insurance policy.

All contracts would specify a time line for completion of the job specified (example, product or services to be provided). Such contracts need to include conditions, when undue delay in supply of products or services occur; the delay may result in imposition of penalties (fine, or cancellation of the contract).

h) **Publications:** In specific cases, one pharmaceutical company may enter into a contract with another, for a research project. Herein, the "publication clause" is an essential component, whereby one party may restrict the other party, from publication(s), and may impose restrictions such as prior review, maintaining standards, etc.

i) **Limitation of Liability Clause:** Frequently, in a contract, one party may fail to perform its duty, or there may be an undue lapse. When the value of the subject matter is very high in the contract, this may result in high losses to the other party. In such cases, the affected party may seek compensation from the failing party. For example, when a pharmaceutical company enters into a contract with another company, say, for handling of a sophisticated, costly equipment and the second party fails to perform its duty, this may result in heavy losses to the pharmaceutical company. Here, the second party may have been charging only a small fee for handling of the equipment, but it may be faced with heavy compensation claim from the pharmaceutical company. Thus, the company, before signing the contract, may wish to include a clause for limitation of its liability, so as to avoid very heavy damages or compensation claims, in case of non-performance its duties.

j) **Audits & Inspection Rights:** In every commercial contract, usually a clause with respect to timely audits and inspections, would be included, setting out the rights and obligations of the parties involved. Thus, one party may be required to allow entry of officers or auditing bodies (from the second party) to enter the premises, inspect materials, documents, accounting books, etc. and providing adequate workspaces. Also, any discrepancies / deviations in the accounts (or procedures) may also be required to be disclosed at the time of the audit. (12)

15.2 Some of the leading case studies in Law of Contracts:

- The Carbolic Smoke Ball Company Case (1893): This landmark case is often cited as a prime example of an offer made by a company, to the world at large, through advertisements.
- Hadley v Baxendole (1854): This case is significant in determining the measure of damages for breach of contract.
- Partridge v Crittenden (1968): This case explained the distinction between an invitation to treat and an offer.
- Felthouse v Bindley (1862): This case established the principle that silence or inaction cannot constitute acceptance in contract law.
- Fisher v. Bell (1961): This case explored the concept of an invitation to treat in the context of display of goods.
- Donoghue v Stevenson (1932): Although primarily a tort law case, this case expanded the principles of negligence and established the concept of duty of care in contract law. (13)

16. Conclusion

It is evident that Law of Contracts lies in the heart of the pharmaceutical industry, covering its day-to-day transactions. The utility of Law of Contracts has been demonstrated in USA, EU and India, in this article. The application of Law of Contracts has been illustrated at various stages in a pharmaceutical industry, right from its conception, day-to-day working and its closing. Different types of contracts, as recognized in law, have been described, with a particular focus on pharmaceutical industry, along with the key types of agreements in pharmaceutical industry. Key considerations which need to be looked into in these contracts have been described, along with some leading case studies in each type of contract. Common clauses in the different types of contracts have been described. A perusal of the contents of this article is sufficient to emphasize the essential role of Law of Contracts in pharmaceutical industry. The authors conclude that it would be prudent to include the study of Law of Contracts in Pharmacy Curriculum in India, both

at UG and PG level, and particularly for PG course in Drug Regulatory Affairs. This would sufficiently enrich the Pharmacy graduates and post graduates, to become acquainted with the fundamentals of Law of Contracts, and prepare them in a better way to deal with the various contracts in the pharmaceutical industry.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Reference

1 Modi N. India: The World's Pharmacy -- Prime Minister Narendra Modi [Internet] Press Information Bureau;2024 Aug 22 (cited 2025 Aug. 01). Available from: https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=152038&ModuleId=3

2 Bangia RK. Contract – I (Law of Contract-I with Specific Relief Act), Chapter I: Formation of Contract, page 1. Allahabad Law Agency, Faridabad; 2005.

3 Pharmaceutical Contracts: GMP and Legal Compliance [Internet], ESKAG Pharma Global Division; 2025 Feb 06 (cited 2025, Sept 05). Available from: https://www.linkedin.com/pulse/pharmaceutical-contracts-gmp-legal-compliance-eskagglobal-6dgcc/.

4 Mahawar S. Contracts in the pharmaceutical industry and the clauses covered under it [Internet]. iPleaders Blog; 2022 March 16 (Cited 2025 May 01). Available from: https:// https://blog.ipleaders.in/contracts-pharmaceutical-industry-clauses-covered-under-it/

5 Types of Agreements in the Pharmaceutical Industry [Internet] Medicef pharma, blog; 2024 (Cited 2025, Aug. 05). Available from: https://www.medicefpharma.com/blog/types-of-agreements-in-the-pharmaceutical-industry/.

6 Shyama N. Standard Form Contracts- A Comprehensive Analysis [Internet] Legal Service India.com; 2021 (cited 2025, July 17). Available from: https://www.legalservicesindia.com/article/1161/Standard-Form-Contract.html#google_vignette

7 Annual Reports. Pfizer Inc., 2007 Financial Report [Internet] Annual Reports.com; 2007 (Cited 2025, Aug. 05). Available from: https://www.annualreports.com/HostedData/AnnualReportArchive/p/NYSE_PFE_2007.pdf.

8 Rai MM. Sun Pharma Laboratories Ltd vs Union of Indian And Ors, Sikkim High Court [Internet]. India Kanoon; 2021 Feb 05 (cited 2025, Aug. 06). Equivalent citations: AIRONLINE 2021. Available from: https://indiankanoon.org/doc/24887611/

9 Ashok KM. Promissory Estoppel Would Not Apply Against the Exercise of Legislative Powers Of The State: Supreme Court [Internet] Live Law.in; 2022 Oct 17 (cited 2025, Aug. 05). Available from: https://www.livelaw.in/top-stories/supreme-court-promissory-estoppel-legislative-powers-hero-motocorp-ltd-vs-union-of-india-2022-livelaw-sc-852-211887.

10 Verma VK. M/s Motilal Padampat Sugar Mills v. State of Uttar Pradesh & Ors. [Internet]. Indiacaselaw.in,; 2013 Jan 15. (cited 2025 July 02). Available from: https://indiancaselaw.in/ms-motilal-padampat-sugar-mills-v-state-of-uttar-pradesh-ors/.

11 Dentro Pharmaceuticals (P) Limited vs The State Of Tamil Nadu And Anr. [Internet]. Indiakanoon; 1994 Sept 29 (cited 2025, July 02). Equivalent citations: (1995)1MLJ444. Available from: https://indiankanoon.org/doc/597872/

12 Sushant MM. Contracts in The Pharmaceutical Industry: Types And Clauses [Internet] Indian Journal of Integrated Research in Law March – April 2022; II(II);364-371. (cited 2025, July 02). Available from: https://doi-ds.org/doilink/03.2022-74756158/IJIRL/V2-I2/A33, ISSN: 2583-0538.

13 Important Case Studies in Contract Law [Internet] Fastercapital; 2025 April 05 (cited 2025, July 18). Available from: https://fastercapital.com/topics/important-case-studies-in-contract-law.html.