Contract Manufacturing Agreement, Principle To Principle And Loan License Agreements Under Drug Laws

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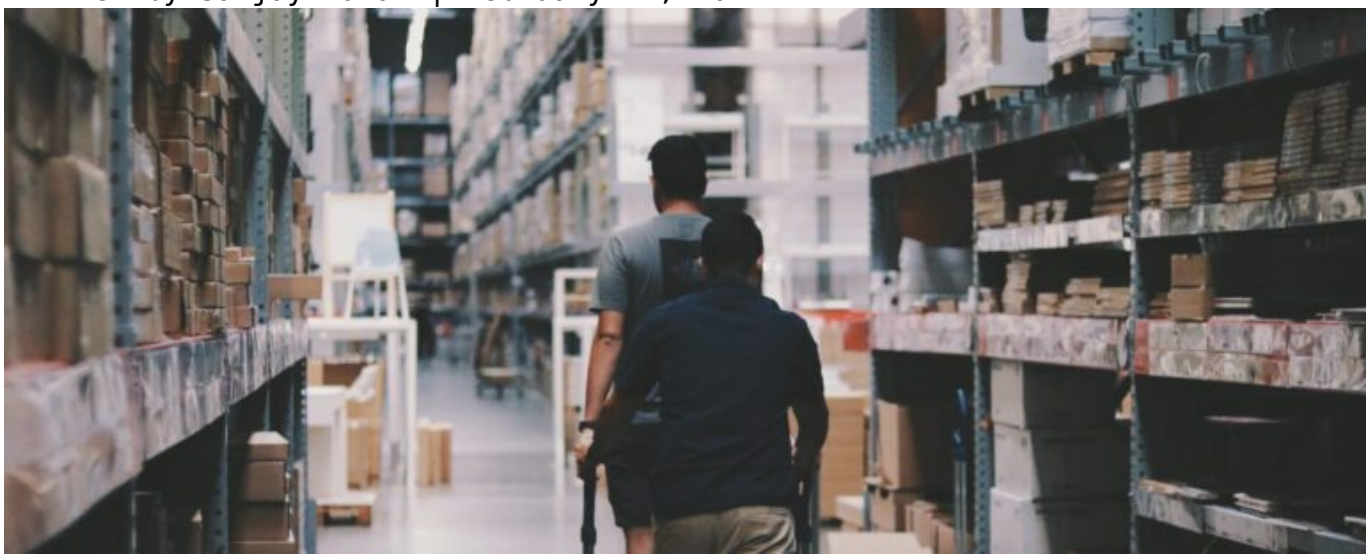

Historically pharmaceutical companies turned to contract manufacturers for achieving efficiencies in cost, capacity and time-to-market, or to obtain specific expertise not available in-house. However, the increment in outsourcing of manufacture is driven, at least in part, by the fact that contract manufacturers have increasingly developed innovative proprietary processes and implemented technology that may well surpass that available at the pharmaceutical (The drugs and cosmetics act 1940 and rules 1945) client's own facilities. Moreover, nowadays few pharmaceuticals are made in dedicated plants and key intermediates and active compounds can be made in general-purpose plants.

Types of Contract Manufacturing: Pharmaceutical companies outsource a wide-range of manufacturing-related activities, including active ingredient manufacturing, formulation, stability testing, manufacturing of chemical intermediaries, primary and secondary packaging, labelling, clinical trial supplies, etc.

Product Liability under Contract Manufacturing: The law relating to product liability in the EU is based on Council Directive 85/374 concerning liability for defective products (Product Liability Directive). In the USA, actions in medicinal product liability cases are mainly brought in tort under state law (negligence, strict liability and a breach of warranty claims). In India, under Section 2(34) of the Consumer Protection Act 2019 "product liability" means the responsibility of a product manufacturer or product seller of any product or service, to compensate for any harm caused to a consumer by such defective product manufactured or sold or by a deficiency in services relating thereto.

The most common defendants in product liability actions are the manufacturer and other pharmaceutical companies that market or otherwise promote the product.

Contract Manufacturing under Drug Laws - The Drugs and Cosmetics Act 1940 and Rules 1945

The Drugs and Cosmetics Act 1940 (“Act”) and the Drugs and Cosmetics Rules 1945 (“Rules”) do not provide any express provision on contract manufacturing arrangement. The Act and the Rule are silent on contract manufacturing arrangement with respect to quality, effectiveness and regulatory compliance.

Third Party Manufacturing or Principle to Principle (P2P) and Loan License Agreements

In India, P2P and Loan License Agreements are very popular manufacturing arrangements. P2P manufacturing agreements are entered in by marketing companies with manufacturing companies for product specification with the manufacture's technical know-how under a specific brand or trademark of a marketing company.

The product is manufactured under license in Form 25 and 28 of the Rules issued from State Food & Drug Administration. The marketing company sells and distributes the products under a wholesale license issued in specific Form 20 -21 from the state FDA. Under P2P agreements, so far marketing company is not responsible for the quality and regulatory compliance of drugs except under the Drug Price Control Order ("DPCO") wherein price of the drugs is declared by NPPA and licensing conditions of the wholesale license.

However, the legal position of the P2P agreement is not correct in terms of liability for quality and regulatory compliance of drugs.

As far as third party manufacturing agreements are concerned, there is no such arrangement in Drugs and Cosmetics Rules, 1945. There are only 3 ways of manufacturing drugs as per Rules:

1. Own Manufacturing Licence
2. Repacking Licence
3. Loan Licence- When anyone wishes to avail oneself of the manufacturing facilities owned by a licensee, one is granted a Loan Licence (25A or 28A)

It was held in *Glaxo Smithkline Vs State of Bihar[1]* that standard & label claims of the product cannot be dictated by a marketing company at its sweet will but must be in accordance with the standard set out in the Second Schedule of Drugs and Cosmetics Act 1940 and labelling Rules 96 & 97 of Drugs and Cosmetics Rules, 1945 respectively.

It was further held that Glaxo as a wholesaler can not infringe the "Labelling process" which comes within the ambit of "Manufacture" as per Section 3(f) of the drugs and cosmetics act 1940 and rules 1945 and concerns manufacturer only not a wholesaler. Therefore, if they wish to print the logo and name of their company on the labels of drugs, they should either manufacture in their own licenced factory or they should get their products manufactured in other licensees "s factory under Loan Licence and not under third party manufacturing agreement.

Getting their products manufactured under third party manufacturing agreement will free them from those legal obligations and responsibilities. All those legal obligations and responsibilities lie on the shoulders of the licenced manufacturer. For the above reasons, Glaxo Smithkline Pharmaceuticals Limited probably resorted to the unfair practice of third party manufacturing.

It was further held that it was evident beyond doubt that the drugs had been manufactured violating the provision of loan licences -Rule 75A and were labelled by violating labelling Rules 96 & 97 of the Rules and logo & name of the intended purchaser (Glaxo Smithkline pharmaceuticals limited - as a wholesaler), as they feature on the labels of drugs & carton of drugs attract the provision of misbranded drug – Section 17(b) & 17 (c) of the the drugs and cosmetics act 1940 and rules 1945.

The petition u/s 482 of Cr.PC was quashed by the Patna High Court and directed for trial at the magistrate court. Later, SLP filed by GSK also got dismissed by the Supreme Court. The matter is currently pending at magistrate

court in Patna.

In order to curb the practice of pharma companies indulging in third party P2P, the Central Government has amended Rule 2 of the Drugs and Cosmetics Rules, 1945 including the term 'marketer' under clause (ea).

The term "Marketer" means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution.

Further, Rule 84D has been inserted which provides an agreement for marketing. This rule makes it mandatory for every marketing company to enter into an agreement for the marketing of the drug. Rule 84 E has been inserted to define the responsibility of the marketer. This equates the responsibility of marketer with a manufacturer for the quality of drugs and regulatory compliance.

Further, a sub-clause clause (xiii) in clause (1) Rule 96 has been inserted regarding the labelling requirement of drugs by marketer. This means that showing the name of the marketer of the drug and its address if the drug is contained in an ampoule or a similar small container, shall be enough.

Loan License Agreement

The term loan licences as mentioned in Rule 75A of Drugs and Cosmetics Rules 1945 reads as under – "*For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee in Form 28.*"

When a company gets its products manufactured in another licensee's factory under a Loan Licence, it has certain legal obligations and responsibilities as prescribed under Rule 76, 76A & 78A of the drugs and cosmetics act 1940 and rules 1945.

A loan license manufacturing agreement is entered by a company that is the marketing authorization holder of a drug duly licensed to manufacture and market. Rule 75A and Form 28 of the Drugs and Cosmetics Rules, 1945 provide this arrangement. Under a loan license agreement, product specification know-how and its trademark are transferred to a manufacturing company to use manufacturing facilities and its staff.

The drug is manufactured under the supervision of a company that has got a Loan License under Form 28. The quality, efficacy and safety are responsibilities of the Loan license holder. The product label clearly describes the product manufactured by the name of loan licensee with the place where the product is manufactured by the licensee manufacturing company.

Conclusion

In the light of the provisions under the Drugs and Cosmetics Act 1940 and Rules 1945 and its amendment of 2020 with effect from 1st March 2021 and the Consumer Protection Act 2019, it is clear that the central government and the drug regulators are keen on fixing responsibilities of a marketing company under a contract manufacturing arrangement in terms of quality, efficacy, safety and product liabilities.

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[1] M/S Glaxo Smithkline vs State Of Bihar & Anr 2011 CrLJ 2553

[2] The Drugs and Cosmetics Act 1940 and Rules 1945

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