CHRIST
(DEEMED TO BE UNIVERSITY)
DELHI-NCR, INDIA

A CASE DIGEST ON

DRUGS & COSMETICS ACT

SCHOOL OF LAW, DELHI NCR CAMPUS

2022-2023

ABOUT SCHOOL OF LAW

School of Law, CHRIST (Deemed to be University) (SLCU), Delhi NCR, is an off-campus CHRIST (Deemed to be University), Bangalore. It already has a proven history of success in the field of education. The School of Law offers Undergraduate, Postgraduate and Doctoral programmes in Law as per the guidelines of the Bar Council of India and the University Grants Commission. It has a flexible curriculum offering several options in different areas of specialization. It is devised keeping in mind the requirements of the legal profession and academia. The academic programmes offered at School of Law incorporate a number of special opportunities such as Internships, Legal Aid, Moot Court, Trial advocacy, Client Counseling, Value-added Courses, Skill Enhancement Workshops, Career-Oriented Training with outcome based legal education.

OBJECTIVE OF CASE DIGEST ON DRUGS & COSMETICS ACT

The Drugs & Cosmetics Act, 1940 is the sole act governing the manufacture, imports and distribution of drugs in India. The recent years, especially after the pandemic, India has witnessed a lot of new players in this industry which makes this Act the centre for every such transaction. Drugs & Cosmetics has become a niche area and therefore School of Law, Christ (deemed to be University), Delhi NCR aims to create awareness and knowledge towards this field of law. This Case Digest has been drafted with the vision and mission to inspire the readers to research further on this area and to foster an innovative academic environment for critical thinking.

SYNOPSIS OF THE DRUGS & COSMETICS ACT

The Drugs & Cosmetics Act, 1940 was formulated after the recommendations of the Chopra Committee constituted by the Union Government in 1930. The Act governs the import, distribution and manufacturing of the drugs and cosmetics and has been drafted with the primary objective of selling only safe drugs and cosmetics which conform to the quality standards laid down by the Act. There are various provisions in this Act in order to hold pharmaceutical companies liable for selling or manufacturing of any substandard drugs and cosmetics or negligence. There are also parallel Drugs & Cosmetics Rules formulated in 1945 in order to facilitate and complement the Act. They enunciate the guidelines in a tabular format for storage, sale, manufacture etc for the mentioned drugs and cosmetics. It is a comprehensive legislation which aims to effectively regulate the pharmaceutical industry in India. Therefore, these regulations should be complied with for the welfare and interest of general public.

FAIR PRICE OF DRUG SAMPLES

Vivek Pharmachem (India) Ltd. v. State of Rajasthan & Ors. 2020 SCC Online Raj 1465.

Relevant Provisions: Sections 18A & 23 of the Drugs & Cosmetics Act, 1940.

The background leading to this petition under Article 226 of the Constitution of India is that the Drug Inspector sent a notice to the petitioner on 23.12.2020 stating therein that certain Drugs were seized from the Drug Store Community Health Centre, Kota and the house keeper informed that he had procured the said Drugs from the District Drug Warehouse, Kota and DDW informed that the petitioner is manufacturer of the said Drugs. The Inspector informed to the petitioner that the Drugs were not of standard quality, for the reasons mentioned in the notice. The petitioner filed an application before the Chief Judicial Magistrate, Kota for supplying one portion of the sample of the Drugs out of total four samples required to be prepared in view of the provisions of Section 23(3) of the Drugs and Cosmetics Act, 1940. The major issue highlighted was where an Inspector takes any sample of a drug under him, shall he be liable to tender the fair price thereof and require a written acknowledgement?

The Court observed in this case that it is clear that under Section 18A name of the petitioner was disclosed as manufacturer. Therefore, petitioner was entitled for a part of seized sample under Section 23(4)(iii) of the Act. It is held that both the Courts have failed to exercise jurisdiction vested leading to miscarriage of Justice, hence, the impugned orders are not sustainable. They are hereby quashed accordingly, and it is directed that the petitioner be supplied with a part of the sample seized under the Act.

STATE REP. BY THE SENIOR DRUGS INSPECTOR V. SUBIKSHA TRADING SERVICES PVT. LTD 2022 SCC ONLINE MAD 3403.

Relevant Provisions: Sections 18(c) of the Drugs and Cosmetics Act, 1940 r/w 65(6), 65(4)(3)(ii) and 65(4)(4) of Drugs Rules 1945.

The Senior Drug Inspector inspected the company of accused 1(company), 2(Managing Director), and 3(Manager) and found that the carbon copies of the sales bills for the period 01.01.2000 till date, were not maintained. Similarly, the purchase bills for tablets Rantac 15 mg, Daonil tablets, and Metformin 500 mg tablets (Cipla) were not available. The inspection was conducted based on a specific complaint from one Muthu Kumar alleging that when Dr. K. Balachandran, Senior Civil Surgeon, prescribed Glyciphage and Zinetac 150 mg for his ailment. The 1 respondent firm sold to him Metformin 500 (Cipla) and Rantac 150mg dated 15.11.2000. The major issue highlighted was whether it is the responsibility of the licensee to maintain a carbon copy of cash or credit memos and maintenance of records on the purchase of drugs intended for sale?

The court observed that it is the responsibility of the licensee to maintain a carbon copy of cash or credit memos and maintenance of records on the purchase of drugs intended for sale is vested. The court further guided that, even if the Pharmacist is responsible for documentation, the primary responsibility of the licensee is to maintain carbon copies of sale bills and records of purchase.

PROOF OF POSSESSION OF DRUGS

DRUGS INSPECTOR, REP. BY ITS PUBLIC PROSECUTOR V. CHIPPA THIRUPATHI
2022 SCC ONLINE TS 1282.

Relevant Provisions: Section 27(b)(ii), 28 and 22(3) of the Drugs and Cosmetics Act, 1940.

The respondent was found in the premises of door No. 2-215, Chata Village, and in possession of drugs meant for sale, without a valid license. The Drug Inspector in the presence of panch witnesses to the seizure conducted the seizure of the said drugs. The drug inspector seized the drugs in front of the witness and issued notices to verify whether or not he had a license to which the respondent did not reply. The major issue highlighted was whether it is the duty of the complainant to prove beyond reasonable doubt that drugs were seized from the possession of the respondent/accused in his premises?

The court observed that it is the duty of the complainant to prove that the drugs were in the possession of the respondent within his or her premises.The court further guided that when there is no corroboration by oral or documentary evidence, to support the version of P.W.1 that drugs were seized from the possession of the respondent/accused in his premises then in that case PW1's version cannot be believed. Accordingly, the appeal filed by the State failed and the same was dismissed.

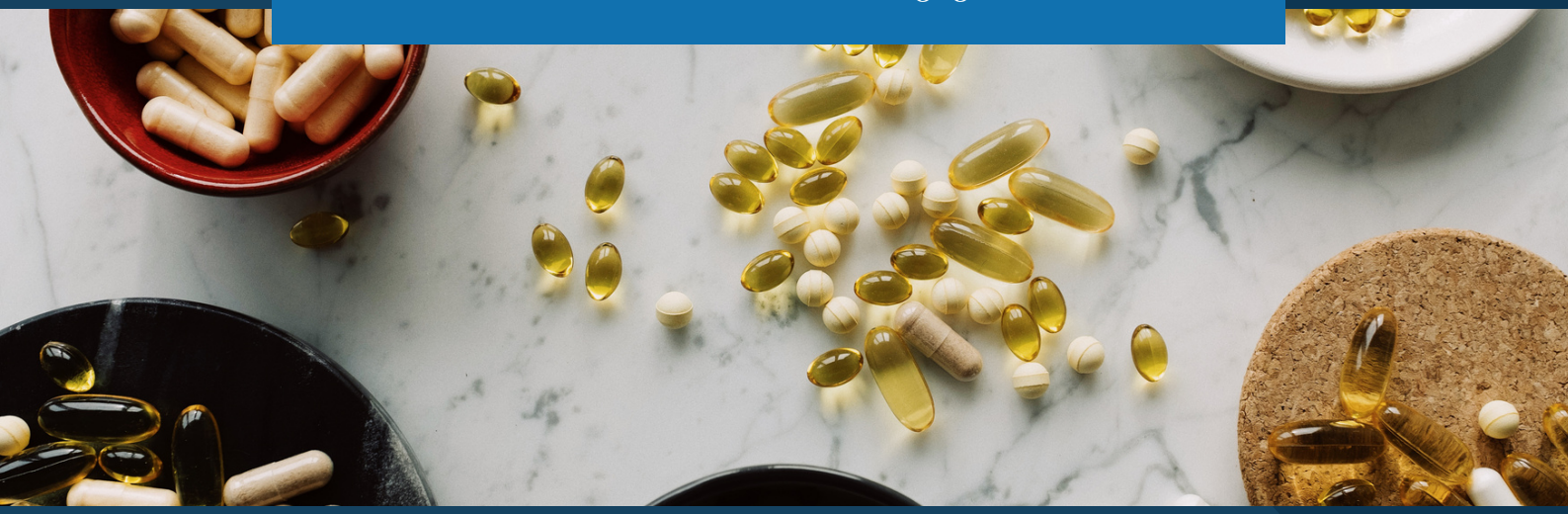
DR. S. ATHILAKSHMI V. STATE REP. BY THE DRUGS INSPECTOR
2022 SCC ONLINE MAD 3254.

Relevant Provisions: Sections 27(b)(ii) and 18(c) of the Drugs and Cosmetics Act, of 1940.

The respondent filed a complaint for the contravention of Section 18(c) of the Act, punishable for the offences under Section 22(b)(ii) of the Act. The petitioner was found stocking and selling (without sales bills) without holding any drugs license. The learned counsel appearing for the petitioner submitted that the petitioner is working as an Assistant Professor and Civil Surgeon at Royapettah Medical College, Chennai and she can do her practice & dispense medicine to her patients and therefore cannot be prosecuted under Section 21(b)(ii) of the Act. Rule No. 6.3 of the Medical Council of India Rules enables the doctor to cause the dispense of medicine to their own patients. Mere possession of bills does not mean that the petitioner is selling the medicines at an open separate counter. The major issue highlighted was whether a medical practitioner can be involved in the sales of drugs without a bona fide license?

The court observed that though the petitioner is a practicing doctor, the registered medical practitioner can keep medicines under Item 5 of Schedule "K" of the Act subject to certain conditions. The provision is very clear that the medical practitioner should not keep an open shop, selling across the counter, and engaged in the importation, manufacture, distribution, or sale of drugs. Whereas the petitioner had sold the drugs under various sales bills as she was engaged in sales where no exemptions were provided under Schedule K of the Drugs and Cosmetics Rules. Hence a medical practitioner is required to acquire a bona fide license for involvement in the sales of the said drugs. Accordingly, the Criminal Original Petition stands dismissed. Consequently, connected Miscellaneous Petitions are also closed.

LALANKUMAR SINGH V. STATE OF MAHARASHTRA
2022 SCC ONLINE SC 1383.



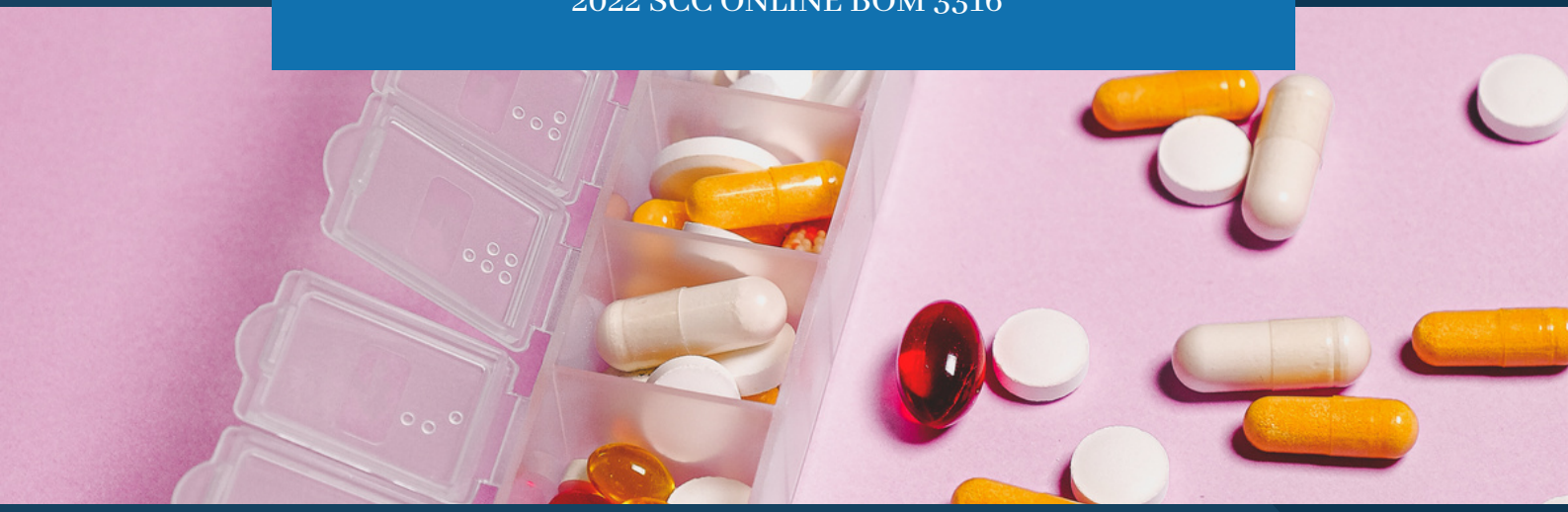
Relevant Provisions: Sections 34 of the Drugs and Cosmetics Act, 1940 & Section 18(a)(i) read with Section 16 of the Drugs and Cosmetics Act 1940

The appellants are the directors of Cachet Pharmaceuticals Ltd (CPPL) who had license to manufacture "Hemfer Syrup" under Schedule C & C (1) of Drugs and Cosmetics Rules, 1945. When the Drug inspector tested the said Drugs, it was found to be of sub-standard quality as the content of Cyanocobalamin was less than the permissible limit. The appellants claimed that Hemfer Syrup was manufactured under the guidance of an FDA approved manufacturing chemist and complied all the requisite standards. The major issue highlighted was whether the Directors of CPPL liable for manufacture, sale and distribution of 'Hemfer' Drug under S.34 of the Drugs and Cosmetics Act 1940?

The Court observed that all the Directors were engaged in the business of CPPL and thus, they were involved in the manufacturing process. It was held that merely because a person is a director of a company, it is not necessary that he is aware about the day-to-day functioning of the company. Appellants are neither the managing director nor the whole-time directors of the accused company. The drugs were tested by a licensed chemist. The order is liable to be set aside if no order of issuance of process given by the lower court and no reasons are given therein while coming to the conclusion that there is a prima facie case against the accused. The appeal is allowed and the orders of CJM and High Court is quashed and set aside. Complaint against appellants is dismissed.

SUSPENSION OF LICENSE-

RAJ PHARMA V. STATE OF MAHARASHTRA
2022 SCC ONLINE BOM 3316



Relevant Provisions: Rules 65(5)(1), 65(3), 65(9)(b) and 65(6) of the Drugs and Cosmetics Rules, 1945.

M/s. Raj Pharma, the petitioner is a partnership firm who holds a valid license to run a pharmaceutical shop under the Drugs and Cosmetics Act 1940 and under Drugs and Cosmetics rules 1945. After an inspection the Licensing Authority (Respondent 2) found certain violations prescribed by the Rules and issued a show cause notice to the petitioner. The petitioner replied to the notice and produced all the required documents and it was contended that there was no violation. But the respondent 2 under rule 66(1) suspended the petitioner's license for 60 days. The appeal under rule 66(2) was before respondent no 1. It reduced the period of suspension from 60 days to 10 days. Aggrieved the petitioner filed a writ petition challenging the order. The major issue highlighted was whether the suspension of the license by the authority valid?

The Court observed that so far as the charge of not providing details of sale under sub sections under Rule 65 is concerned the petitioner had provided all the details to the Licensing authority and the petitioner has not hided any facts or documents from the authority. The substantial details given by the petitioner have not been considered by Licensing Authority and which ought to have been considered before passing the original order of suspension. The first Appellate Authority has also not considered the Petitioner's grievance in the light of the statutory provisions Both orders passed by Respondent No. 2 Licensing Authority and Respondent No. 1 respectively was set aside. The show cause notice was also dismissed. Therefore, principles of natural justice has to be observed under all circumstances.

NITIN RAOJIBHAI DESAI V. STATE OF JHARKHAND AND ANOTHER 2022 SCC ONLINE JHAR 1167.

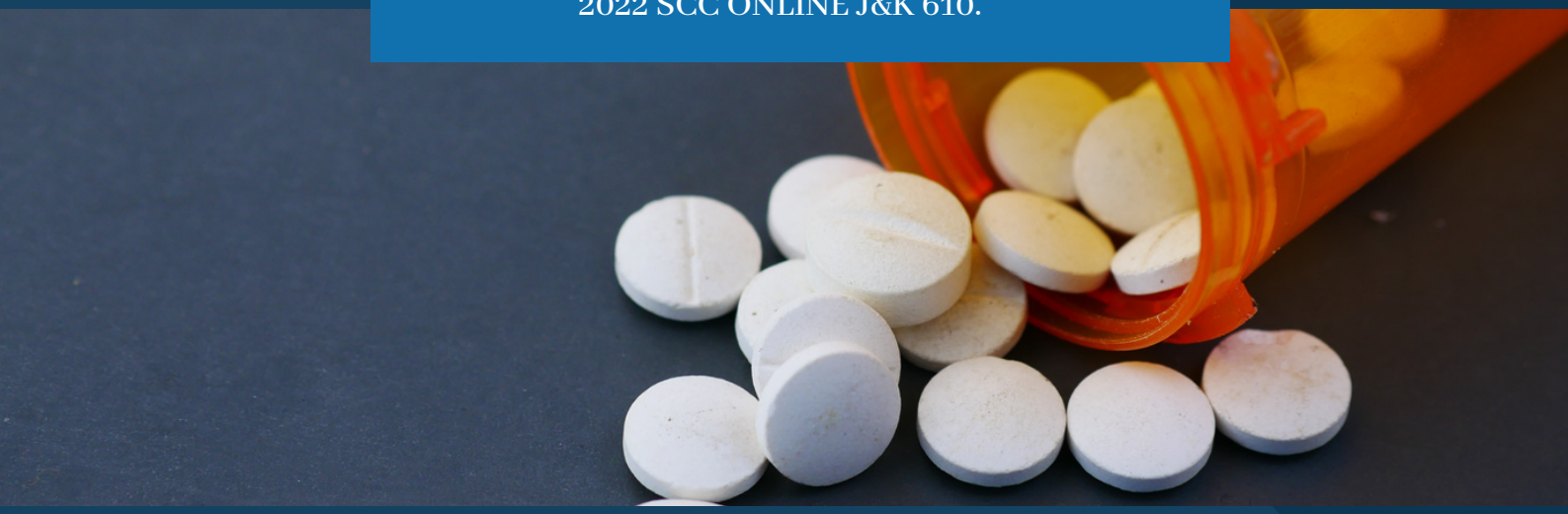
Relevant Provisions: Sections 17, 18(a) (i) and 27(d) of the Drugs and Cosmetics Act, 1940.

The complaint has been filed alleging therein that 3 batches of Zyrop 2k injection and Zyrop 4k injection were inspected at the premises of the warehouse and found that the storage instruction on the inner zipper that the medicine is to be stored at 2 degree Celsius to 8 degree Celsius is not given on the outer package therefore the medicine labelling norms are violated and the medicine is misbranded. Petitioner submits that he is an independent director and there are no averments that he is looking after the day-to-day affairs of the company. As per Section 34, he is not vicariously liable, as the company is not made accused and in view of the above judgments, this petition is fit to be allowed. Respondents contended that as per Section 34, any offense under this Act committed by any person the in charge responsible for the day-to-day affairs of the company as well as the company shall be deemed to be liable and punished accordingly. The major issue highlighted was whether cognizance taken under section sections 17, 18(a) (i) and 27(d) of the Drugs and Cosmetics Act, 1940 against the Director of the company valid?

The Court observed that in the complaint, there is no averment as to what the role played by the petitioner, who happened to be the Director of the said company. If the company is responsible, it is required to be made an accused in the case and in this case, the company has not been made an accused. The court ruled that all the orders of cognizance and the criminal proceedings should be quashed. The court ruled that continuance of the criminal proceedings on the basis of the impugned complaint against the petitioners would be an abuse of the process of law as there are no chances of their conviction on the basis of the allegations made in the impugned complaint, hence the petition was allowed and the proceedings emanating therefrom as against the petitioners were quashed.

IMPLEADING OF THE COMPANY

ASHISH DAMIJA V. UT OF J & K
2022 SCC ONLINE J&K 610.



Relevant Provisions: Section 18(a)(i) read with Section 17(B)(d), 27(c), 36-AB, 124B and Schedule V S. No. 3 of the Drugs and Cosmetics Act, 1940.

During the investigation, it was found that the drug in question has been manufactured by M/s. Adwin Pharma Village Rampur District Sirmour, Himachal Pradesh. it was reported by the Central Drugs Laboratory, Kolkata, that the sample is not of standard quality. Accordingly, the prosecution was launched against the petitioners and other co-accused who happen to be the distributors and retailers of the drug in question. The major issues highlighted was Whether the provisions under section 34 apply to partnership firms? & Whether the Directors or person in charge of the affairs of a company can be launched without impleading the company as an accused in a case where the statute provides for vicarious liability of the person in charge of the company for the offenses committed by the company?

The Court observed that without impleading the company as an accused, its Directors or persons responsible for the conduct of its day-to-day business cannot be prosecuted for an offense that is deemed to have been committed by the company. The requirement of impleading a company as an accused in a prosecution where the offence is alleged to have been committed by the company is equally applicable to a partnership firm and the firm has to be impleaded as an accused along with the partner who is responsible for the conduct of the business of the said firm. The court ruled that the respondent has impleaded only the partners of the manufacturing firm M/s. Adwin Pharma without impleading the firm as an accused in the complaint. Thus, on this ground alone, the proceedings against the petitioners are not sustainable.

MERCK SHARP AND DOHME CORP. V. SMS PHARMACEUTICALS LTD
(2021) 3 HCC (DEL) 45

Relevant Provisions: Section 107 A, The Patents Act, 1970 & The Drugs and Cosmetics Act, 1940: approval by relevant authority for manufacture.

In the case, the plaintiff, Merck Sharp and Dohme Corporation had sought injunction against the manufacture and distribution of a certain anti-diabetic drug, Sitagliptin by the defendant alleging the infringement of their patent. The plaintiff stated that Sitagliptin Hydrochloride was advertised for sale in the defendant's list of active pharmaceutical ingredients (APIs) and analytical standards. They further claimed that the export of APIs by the defendant to foreign companies, Chemo and Verban makes it impractical for the plaintiff to identify whether the drug is being utilized for R&D purposes or being commercially exploited. The major issue highlighted was whether API Sitagliptin be permitted to be exported to Chemo and Verben by the defendant, MS Pharmaceuticals Ltd?

Relying on the judgement of Bayer Corporation v. Union of India, the Court observed that the mere possibility of commercial exploitation by the foreign entities cannot serve as a rationale for withholding benefits provided under Section 107A of Patents Act to the defendants. Thus, the court granted the defendant's request to export the APIs to Chemo and Verben, provided, the defendant files an affidavit with the Court explicitly specifying the amounts of Sitagliptin that will be exported and that it would be utilized solely for R&D purposes. The court also ordered to implement all the measures established in the case of Bayer Corporation.

VIMAL KUMAR KHEMKA V. DRUGS INSPECTOR
2021 SCC ONLINE KER 5610

Relevant Provisions: Sections 18(a) (i), 27 & 34 of Drugs and Cosmetics Act.

It was claimed that the petitioners had manufactured and sold 10 ml Hypodermic single-use syringe which were not sterile or clean and failed to meet the sanitary standards. Reports from Government Analyst Drugs Testing Laboratory, Thiruvananthapuram and The Central Drug Laboratory, Calcutta were used to validate these claims. The allegations made in this case were that the petitioners were the "manufacturers and sellers" of the syringes and were thus liable under Section 34 of the Drugs and Cosmetics Act, 1940. The contentions raised by the petitioners was that they were the Directors of the company and that nothing was stated in the complaint that apart from being the Directors of the aforesaid company, they were, at the time of the alleged commission of the offence, in-charge and were responsible to the company for the conduct of the business of the first accused/company. The arguments made by the defendant was that The company is a legal entity without life and blood, and there should be persons who are entrusted with the management of the affairs of the company and the functioning of the business of the company.´Thus, the petitioners as Directors were responsible for the activities of the Company. The major issue highlighted was whether the petitioners will be held liable as Directors of the company for malpractice?

The Court observed that the petitioners as Directors were particularly averred in the complaint to be accountable for the conduct of the company's operations. A simple statement that they were the persons manufacturing the hypodermic syringes, was found to be below standard and insufficient to comply with Section 34 of the Act. Thus, the Order on the files was quashed under Section 482 of the CrPC, 1973 and the accused were discharged. Subsequently, all the pending interlocutory applications were closed.

CLASSIFICATION OF KADRIPOL

STATE OF GUJARAT V. CADILA HEALTHCARE LTD.
2022 SCC ONLINE SC 851

Relevant Provisions: Schedule II Part A of the GST Act, Drugs and Cosmetics Act, 1940.

The case stems from Deputy Commissioner of Sales Tax issuing a Determination Order stating that Kadiprol is a "Drug and Medicine" under Schedule II Part A of the GST Act. Cadila applied with the Deputy Commissioner to ascertain its tax rate. The company applied to get a licence under the Drugs and Cosmetics Act, 1940, in order to manufacture the product. However, Kadiprol was declared a drug by the Deputy Commissioner of Revenue (GST) under the Drugs and Cosmetics Act, 1940. Later, the tax office ruled in 1990 that the product contains some preventative medication and is thus classified as a drug under the GST Act. The High Court ruled in favour of the company, declaring that the product will be classified as “Poultry Feed” under the GST Act. The State Tax Office filed an appeal with the Supreme Court in response to this order. The major issue highlighted was whether Kadriprol is classifiable as “poultry feed” or as “Drug and Medicine”?

The Court observed that the product in question was sold in a sachet of 100 gm. It was required to be mixed with the feed given to the poultry/birds. It was not intended to be fed to the birds. It could not be fed to the birds directly. Thus, the issue is in the academic interest, with no revenue implications because there were no tax dues and hence no tax consequence. Thus, the proceedings were closed, keeping the question on Common Parlance Test open to be referred to in matters of similar nature in the future.

VIKAS RAMBAL AND OTHERS V. STATE REP. BY, DRUGS INSPECTOR
2022 SCC ONLINE JHAR 1167

Relevant Provisions: Sections 18(a)(i), Section 27(d), Section 37(d), Section 32 of the Drugs and Cosmetics Act, 1940.

A drug manufacturing company consisting of 4 directors manufactures a drug named Carbimazole Tablets. This drug is supplied to the medical store of Government Hospital, Tiruppur. During a surprise inspection it was found that the drugs supplied to the medical store are not of standard quality. Hence, after conducting enquiry and affording opportunity to the Company, prosecution had been launched against the said Company and its Directors. The major issue highlighted was whether the accused are liable under Section 32 for the violation of Section 18(a)(1) of Drugs and Cosmetics Act, 1940?

The Court observed that the decision to manufacture medicines is a collective decision of the board of directors. Therefore, the directors cannot claim that they are not directly involved in the drug product when the very decision to manufacture the drug is the result of their decision. When an offense is committed by the Company, all the directors who benefited from the said offense should be prosecuted and all are vicariously liable. They cannot escape criminal liability by naming one of the directors as the person responsible for the offense committed by the Company and are not involved in the day-to-day affairs of the Company. As long as their names are mentioned as the Board of Directors, violation of the provision of the Act concerned with the products criminal liability shall fall on all the Directors for an offense committed by the Company. Hence, all the Directors are liable whether they knew about the crime or directly participated in it.

NEENA GUPTA V. UNION TERRITORY OF LADAKH
2022 SCC ONLINE J&K 609

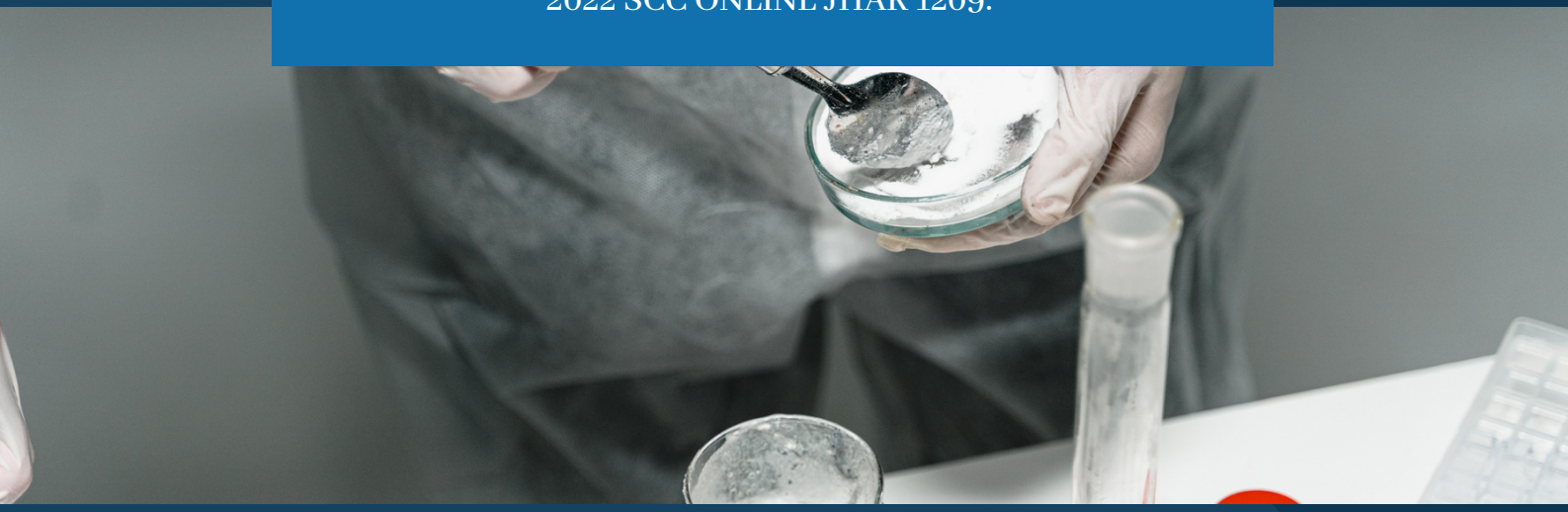
Relevant Provisions: Sections 18(a)(i) & 27(d) of the Drugs and Cosmetics Act, 1940.

The complaint filed by the respondents has been challenged in this case by the petitioners alleging them to have committed the offences under Sections 18(a)(i) r/w 27(d) of the Drugs & Cosmetics Act. They include that there are no specific allegations against them in the complaint as it is not stated they are responsible for the conduct of the business of the firms they are alleged to represent and there is no allegation against the petitioners in the impugned complaint that the drug in question was not properly stored by them. The major issue highlighted was whether the dealer should be held liable for standard quality checks of the drugs?

The Court observed that the complaint alleges that the manufacturer of the drug in question has breached the provisions of the Act by manufacturing and distributing not of standard quality. The report of investigation submitted by the Assistant Drug Controller and the Drugs Inspector is annexed to the impugned complaint. In the inspection report, it has been remarked that since the manufacturing firm has not challenged the test report, their request to drop proceedings against them cannot be considered. The petitioners could not have been prosecuted by the respondent Drugs Inspector because they met the conditions mentioned in Section 19(3) of the Drugs and Cosmetics Act. The prosecution against them is, therefore, unsustainable in law. It is clear that the Drugs Inspector has found that there is no evidence that the drug in question was not stored in a proper condition.

POLICE EMPOWERED TO LODGE COMPLAINT

GANESH PRASAD V. STATE OF JHARKHAND AND OTHER
2022 SCC ONLINE JHAR 1209.



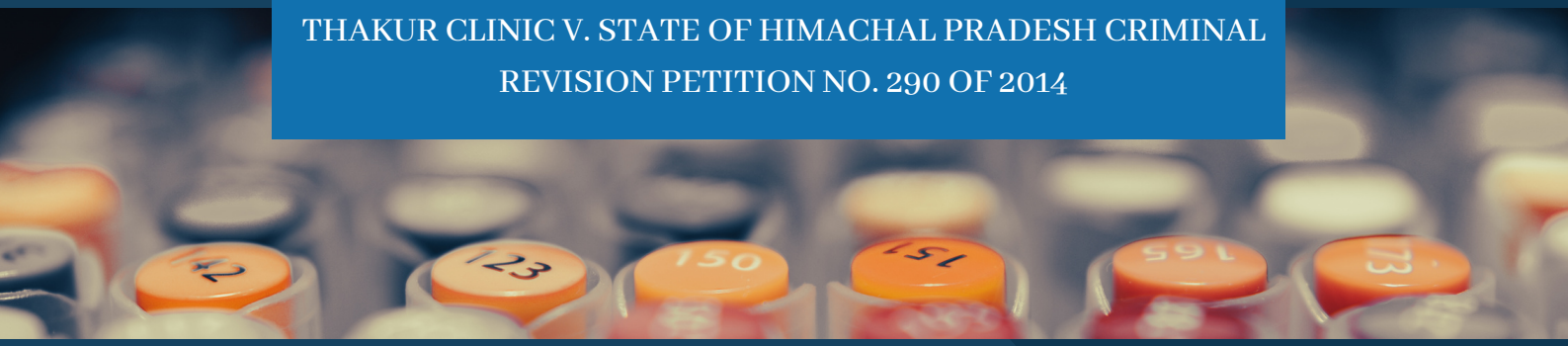
Relevant Provisions: Section 420 of the Indian Penal Code, 1860 and under Sections 18(c), 22 (cca), 27 (B) (II) and 22 (3) of the Drugs and Cosmetic Act, 1940.

The case has been lodged on the basis of the complaint of the Drug Inspector by the Officer-in-Charge, Ratu Police Station. In the joint inquiry, it was found that medicine was wrongly stored and for that, the petitioner has not been able to produce any document. Respondents submitted that that ingredient of section 420 I.P.C. is involved in this case which is why police have investigated the matter. The major issue highlighted was whether a police inspector can lodge a complaint in lieu of a drug inspector for wrong storage of drugs?

The Court observed that the Act provides that an aggrieved person or a member of any association is authorized for filing a complaint case only on the basis of a legally instituted criminal proceeding. If it is not done, the entire criminal proceeding is bad, illegal and without jurisdiction and proceedings are liable to be quashed. Hence the court ruled that the petition should be quashed along with the criminal proceedings.

PROCEDURE TO BE ADOPTED BY DRUG INSPECTOR

THAKUR CLINIC V. STATE OF HIMACHAL PRADESH CRIMINAL REVISION PETITION NO. 290 OF 2014



Relevant Provisions : Sections 22 (1) (cc), 23 & 27of the Drugs and Cosmetic Act, 1940.

The Drug Inspector found allopathic drugs exhibited for sale in the business premises of the petitioner without any license or permission, an apparent violation under section 27 of the Act. The Drug Inspector, seized all allopathic drugs found in the premises of the petitioner and prepared its inventory in Form No.16 and sealed them in two separate cardboard cartons. Independent witnesses were associated, in whose presence seizure and sealing procedure was concluded. The said witnesses turned hostile and alleged that their signatures were obtained on blank papers in good faith and was later produced as their attestation of recovery memo which stipulated list of all the items seized on that day. The major issue highlighted was whether the learned Trial Court and appellate court erroneously upheld the conviction of the petitioners without scrutinizing the validity of the procedure adopted by the Drug Inspector to seize the drugs?

The High Court while exercising their revisionary jurisdiction raised suspicion regarding the manner in which drug inspector seized drugs, documents and corroborated the same with independent witnesses. The document constituting recovery memo required under section 23 runs in two pages and the contents written on second page are in fact on the reverse of first page. One signature was on top left margin of first page and signatures of another witness are on the bottom of the first page on left side. Signatures of other witnesses are on the bottom of second page on left side. Thus, there is no set pattern of getting the signatures of the witnesses on the document. Furthermore, the witnesses hailed from different locations/villages. The documents obtained from the petitioner were not a part of the memo originally and was added to the memo through insertion of serial no. 31, this was corroborated by the fact that during cross examination, respondent didn't suggest the fact that documents were obtained during recovery. On the ground of above stated inconsistencies, the Honorable High acquitted the petitioner.

MOHOMMAD IQBAL MIR V. STATE OF J&K
2022 SCC ON LINE J&K 229

Relevant Provisions: Section 18(c) of Drugs and Cosmetics Act r/w Rule 65(17) of Drugs and Cosmetics Rules, Section 18(c) and Rule 67(17) of Drugs and Cosmetics Act/Rules.

The facts emerging from the record reveal that on 22.06.2013, respondent No. 2 filed a complaint against the petitioner as well as co-accused Jan Mohammad Mir and Bashir Ahmad Mir, before the Court of Judicial Magistrate, 1st Class, Pampore. In the said complaint it was alleged that, while conducting routine inspection of Pampore area on 19.12.2012, one medical shop under the name and style of Fair Price Medical Shop situated at SDH, Pampore, was found indulging in stocking, exhibiting for sale and selling drugs and medicines by way of retail. As per the complaint, Jan Mohammad Mir and Bashir Ahmad Mir are the partners of the aforesaid medical shop. On 08.01.2013, the premises of the shop was again inspected and drugs, bills and physician's sample (not for sale) were found on the shelves of the premises which were seized and, accordingly, permission for prosecution was obtained against Jan Mohammad Mir and Bashir Ahmad Mir. The complaint goes on to allege that the aforesaid two accused have committed an offence by contravening Section 18(c) of the Drugs and Cosmetics Act, 1940, by stocking, exhibiting for sale and selling the drugs and medicines without drug sale license. The major issue highlighted was whether the two accused have committed any offence by contravening section 18 (c) of the Drugs and Cosmetics Act, 1940?

In the instant case, the learned Magistrate had no jurisdiction to try the complaint in question but the record shows that he has not only taken cognizance of the offence but has proceeded to hold trial of the case. On this ground also, the proceedings against the petitioner in the impugned complaint are liable to be quashed. For the foregoing reasons, this petition is allowed and the impugned complaint and the order issuing process, to the extent of petitioner, are quashed.

PENALTY FOR NON-KEEPING OF DOCUMENT AND NON-DISCLOSURE OF INFORMATION

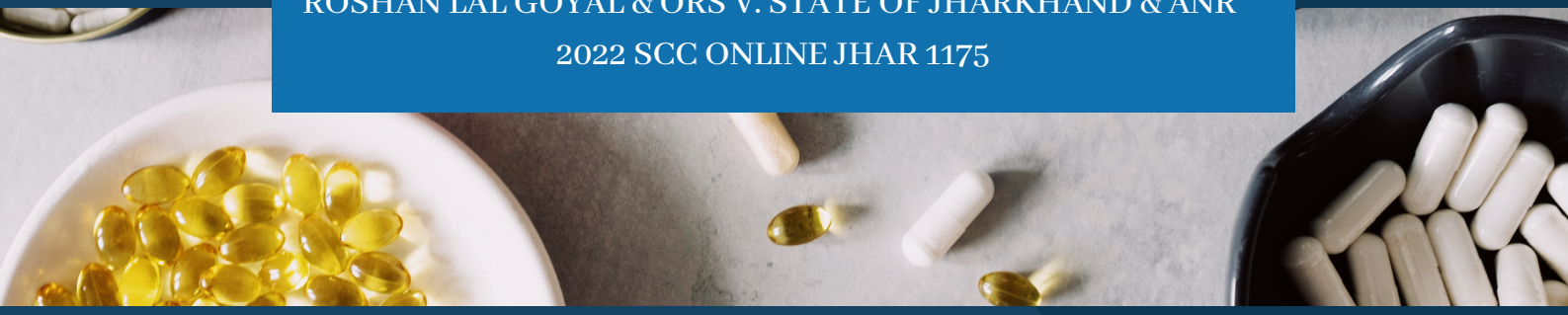
BALBIR V. STATE OF UTTAR PRADESH APPLICATION U/S 482 NO. - 30299 OF 2021

Relevant Provisions: Section 28A of Drugs & Cosmetics Act, 1940.

This application under Section 482 of the Criminal Procedure Code was submitted with a request to halt the entirety of the S.T. No. 50 of 2021 procedure deriving from the criminal no. 316 of 2020 under Section 28A of the Drugs and Cosmetics Act of 1940. All of the arguments presented at the bar center on the disputed factual issue, which this court is prohibited from deciding under Section 482 of the Civil Rules of Procedure. The major issue highlighted was whether penalty should impose against applicant for non-keeping of document and for non- disclosure of information?

Since the case does not fit into any of the classifications recognized by the Apex Court that would allow for their quashing, Court do not see any reason to overturn the FIR, complaint, summons order, or related proceedings against the applicant. It is made plain that the competent court below must proceed according to the law because this court has not made any declarations regarding the case's merits. Therefore, this application has been dismissed.

ROSHAN LAL GOYAL & ORS V. STATE OF JHARKHAND & ANR
2022 SCC ONLINE JHAR 1175



Relevant Provisions: Sections 27(D), 18 (a)(i) of the Drugs and Cosmetics Act, 1940, section 34 of the Drugs and Cosmetics Act, 1940, Section 141 of the Negotiable Instruments Act, 1881.

The complaint has been filed by the Drug Inspector alleging in presence of Child Development and Project Officer, Khuntipani, Store of M/s. Aushadhi Bhandar, ICDS Project, Khuntipani, West Singhbhum was inspected and sample of Paracetamol syrup I.P, B. No. ML12-017 was collected for its examination. The sample was sent to Govt. Analyst, State Medicine Test Laboratory, Namkum, Ranchi, where the chemical examination of the said sample was done and the report dated 22.3.2013 was received and the sample was found not of standard quality as the oral liquid was not homogenous, which duly informed to the CDPO, Khuntipani, Singhbhum West and she was requested to make available the sale register of the said medicine and she was further requested to stop the sale/distribution/use of the said medicine. On 10.05.2013, the representative of the medicine manufacturer company had received a part of the sealed sample. M/s. HLL Life Care Limited, Bekar Bandh, Gupteshwar Complex, Dhanbad on 31.03.2013 had provided the required document to the complainant. The manufacturing and distribution of the sub-standard medicine is hazardous and cognizable offence and therefore the present case has been lodged against the accused persons. The major issue highlighted was whether the company being made an accused in the complaint is vicarious liable or not?

The Court observed that there is no averment as to what are the role played by these petitioners who happened to be Directors of the said company. If the company is responsible, the law is well settled that the company is required to be made accused in the case and in the case in hand the company has not been made an accused. the entire criminal proceeding as well as the order passed by the learned Chief Judicial Magistrate at Chaibasa in connection with Complaint Case pending in the court learned Chief Judicial Magistrate, at Chaibasa is hereby quashed.

HASMUKHLAL D. VORA AND ANOTHER V. STATE OF TAMIL NADU
2022 SCC ONLINE SC 1732

Relevant Provisions: Sections 18(c) & 3(f) of the Drugs and Cosmetics Act, 1940, Section 65 of the Drugs and Cosmetics Rules, 1945.

The Appellant, in the course of their business, purchased 75 kg of pyridoxal-5-phosphate (in the form of 3 x 25 kg packs) from one invoice of M/s Antoine & Becouerel Organic Chemical Co. Drug Inspector conducted an inspection at the premises of the petitioners and alleged violation of Section 18 (c) of the Drugs and Cosmetics Act, 1940, as amended by Section 65 of the Drugs and Cosmetics Rules, 1945. The appellants allegedly broke up large quantities of pyridoxal-5-phosphate and sold them to various distributors. The petitioner is alleged to have divided a large quantity of raw materials into different pack sizes and sold the same to various drug manufacturers. after almost three years, the drug inspector issued a notice to the complainants about the case. The appellants after presenting the matter and submitted their reply to the same. The major issue highlighted in the case was whether there is a violation of Section 18(c) of the Drugs and Cosmetics Act, 1940?

The Court observed that the smaller packages were sold to various other drug manufacturers. This alleged division of the contested substance into smaller packages and its further distribution is classified by the respondent as "production", and therefore proceedings are conducted with the petitioners pursuant to Section 18 (c) as amended with Section 3 (f) of Drugs and Cosmetics Act, 1940. In this case, the Respondent has provided no explanation for the extraordinary delay of more than four years between the initial site inspection, notice of inspection and complaint. However, in such cases, where the accused has been exposed to the fear of possible prosecution for such a long time, it is reasonable for the court to expect only a minimum of evidence from the investigating authorities.

STATUTORY RIGHT OF DRUG MANUFACTURER TO ADDUCE EVIDENCE

SWISS GARNIER LIFE SCIENCES AND OTHERS V. UNION OF INDIA
2022 SCC ONLINE J&K 857

Relevant Provisions: Sections 18(a)(i), 27(d), 23 & 25 of Drugs & Cosmetics Act, 1940.

Sample of Zargo-50 (Losartan Potassium Tab IP) with expiry date of 9/2014 was collected by the drug inspector reported to be of standard quality. The Drugs Laboratory of Kolkata after reanalysis reported that the sample was not of standard quality. The prosecution was launched against the manufacturers of the drugs. The petitioners challenged the complaint. It has been contended that the manufacturer's statutory right to controvert the report of the Government Analyst by adducing evidence but in the current case the said right was violated. No notice had been issued nor was a portion of the sample sent to the petitioners. The complaint had also been filed with no time before the date of expiry of the drug. The major issues highlighted were Whether the sample can be sent for re-analysis after already being tested by the Central Drugs Laboratory? & Whether there is any bar regarding sending sample of drugs directly to the Central Drugs Laboratory? & Whether the right of the manufacturer to adduce evidence would get defeated once the sample is sent directly to the Laboratory?

The Court observed that once a manufacturer or the person from whom the sample was taken notifies his intention of adducing evidence in contravention of the report of Government Analyst, the sample of the drug has to be sent for test or analysis to the Central Drugs Laboratory and once such report is received, the same becomes conclusive evidence. After perusal of sub-section (4) of Section 25, it has become clear that if the sample has already been tested by Central Drugs Laboratory, it cannot be sent for re-analysis to the same or any other Laboratory. No prejudice had been caused to the petitioners even if the complaint was filed when the shelf life was due to expire. It was also held that once the report of the Central Drugs Laboratory was received, there was no provision for the re-analysis of the sample and, as such, the respondent Drugs Inspector had no obligation to give opportunity to the petitioners to adduce evidence in controversion of the said report.

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