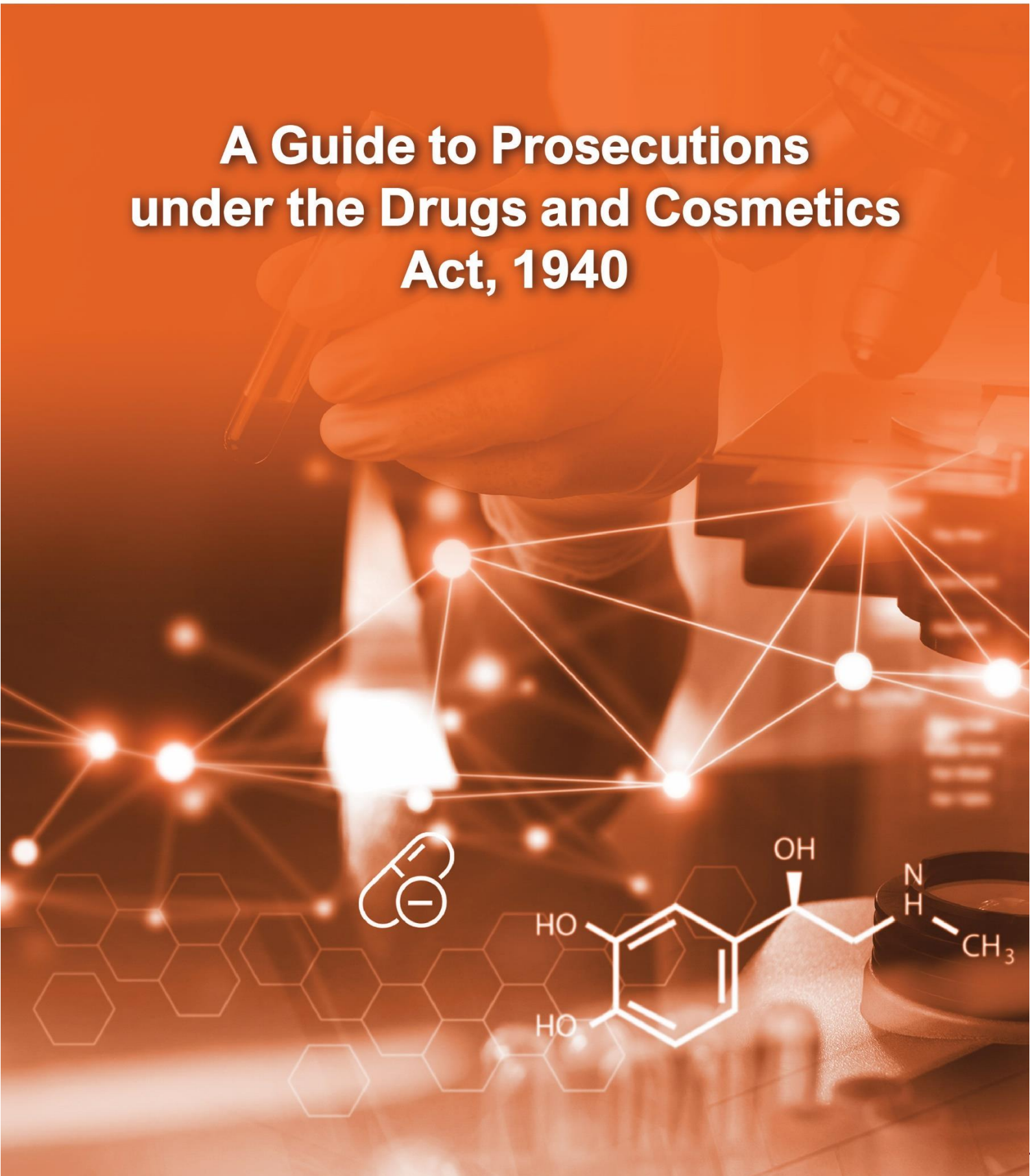
cyril amarchand mangaldas

ahead of the curve

A Guide to Prosecutions under the Drugs and Cosmetics Act, 1940



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A brief introduction

The Drugs and Cosmetics Act, 1940 ("**Act**"), contains a comprehensive legal framework governing the import, manufacture, distribution, and sale of drugs and cosmetic products in India. The Supreme Court[1] has recognised the Act as a special legislation designed in the highest public interest, specifically relating to health, which is linked to the fundamental right to life under Article 21 of the Constitution of India.

The Drugs and Cosmetics Act, 1940, governs the import, manufacture, distribution, and sale of drugs and cosmetics in India and is intrinsically linked to the fundamental right to life under Article 21 of the Constitution.

Scope and Application of the Act

The Act focuses on ensuring the standard and quality of drugs and cosmetics manufactured in the country and regulates the import, manufacture, sale, and distribution of drugs and cosmetics.[2] It imposes punishments and penalties for the manufacture or sale of adulterated or spurious drugs or cosmetics, or drugs or cosmetics not conforming to prescribed quality or standards, especially those that could cause death or grievous hurt to the user. It also seeks to regulate (i) manufacturers, (ii) importers, (iii) distributors,

Scope of the Act

- Ensures the standard and quality of drugs and cosmetics manufactured or sold in India.
- Regulates the import, manufacture, sale, and distribution of drugs and cosmetics.
- Aims to prevent harm by prohibiting the manufacture or sale of
  - Adulterated or spurious products
  - Items not conforming to prescribed standards
  - Products that may cause death or grievous hurt to user

Application of the Act

- Applies to and regulates
  - Manufacturers
  - Importers
  - Distributors
  - Loan licensees
- Covers
  - Drugs as defined under Section 3(b)
  - Cosmetics as defined under Section 3(aaa)

[1] *Union of India v. Ashok Kumar Sharma, (2021) 12 SCC 674*
[2] *Indian Chemical and Pharmaceutical Works v State of Andhra Pradesh, 1965 SCC OnLine SC 65*

(iv) loan licensees of drugs as defined under Section 3(b) of the Act[3] and of cosmetics as defined under Section 3(aaa) of the Act.

"Manufacturer" under the Act

The term "manufacturer" is not defined in the Act; however, the definition for the term "manufacture" in Section 3(f) of the Act is wide, expansive, and inclusive.[4] It includes the process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up, or otherwise treating or adopting any drug or cosmetic with a view of its sale or distribution. The definition does not include the compounding or dispensing of any drug or the packing of any drug or cosmetic in the ordinary course of retail. Consequently, the term "manufacturer" includes within its fold all entities involved in these processes, making them applicable to the stipulations of the Act.

Gleaned from the definition of "manufacture" in Section 3 (f), the term "manufacturer" includes an entity engaged in any process of the making, altering, ornamenting, finishing, packing, labelling, breaking up, or otherwise treating or adopting of a drug or cosmetic for sale or distribution.

- ***Insight:*** Under the Act, the definition of "manufacture" also extends to the repacking of drugs. In a case where a sample of the drug "potassium bicarbonate" was found to be sub-standard, the accused contended that since they were only repacking the drugs received in bulk quantity from the original manufacturer, they could not be held liable for the drug being substandard. Rejecting this contention, the Karnataka High Court[5] held that repacking drugs from bulk to retail size amounted to "manufacturing" as defined under Section 3(f) of the Act. The Court confirmed that re-packers of drugs were also manufacturers under the Act and were responsible for the quality of the repacked drugs.

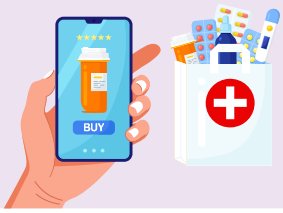
Applicability of the Act and the rules framed thereunder to online pharmacies in India

The Act and the rules framed thereunder do not distinguish between the conventional and "over-the-internet" sale/ distribution of drugs. The Drugs Controller General of India, through a notification dated December 30, 2015, requested all the State and Union Drugs

[3] *Kamala Agencies v. State of Odisha, 2022 SCC OnLine Ori 2451*
[4] *Inox Air Products Ltd. v. State of Andhra Pradesh, 2025 SCC OnLine SC 209*
[5] *State of Karnataka v. Vikram Chemical Laboratories, 1974 SCC OnLine Kar 196*

Controllers to exercise strict vigil over the online sale of medicines and take actions against violations of the Act and rules thereunder.[6]

The 2018 Draft Amendment (not yet in force) defines "**e-pharmacy**" as the business of distribution, sale, stock, exhibition, or offer for sale of drugs via web portals or electronic modes.



On August 28, 2018, the Ministry of Health and Family Welfare published the draft notification seeking an amendment to the Drugs and Cosmetics Rules, 1945, for incorporation of provisions to specifically regulate the sale of drugs via e-pharmacies ("**2018 Draft Amendment**").[7] The 2018 Draft Amendment sought the insertion of a Chapter specifically outlining the provisions governing the sale of drugs by e-pharmacies. The 2018 Draft Amendment also sought to include within the ambit of "e-pharmacy", the business of distribution or sale, stock, exhibition, or offering for sale of drugs through a web portal or any other electronic mode. The 2018 Draft Amendment required e-pharmacies to obtain the requisite registration under the Drugs and Cosmetics Rules, 1945, before undertaking any activity of distribution or sale, stocking, exhibiting, or offering for sale any drugs through e-pharmacy portals. It also proposes stringent requirements for the operation of e-pharmacies, such as maintenance and protection of patient confidentiality; adherence to the Information and Technology Act, 2000 and Rules; maintenance of details such as name, address, and sale licence number of the licensee dispensing the drugs against the prescription uploaded on the e-pharmacy portal; details of the drugs dispatched against the prescription including the name, quantity, batch number or lot number, date of expiry, and name of manufacturer; name and address of e-pharmacy registration and registration number along with the signature / digital signature of the registered pharmacy in charge, etc. Among other things, the 2018 Draft Amendment seeks

Requirements under 2018 Draft Amendment

- Maintain and protect patient confidentiality.
- Adhere to the Information Technology Act, 2000.
- Record specifics of:
  - Dispensing licensee: name, address, and sale licence number.
  - Drug: name, quantity, batch/lot number, expiry date, manufacturer.
  - E-pharmacy: registration details and digital signature of responsible pharmacist.

[6] *Drugs Controller General of India, Reference No. 7-5/2015/Misc/e-Governance/091 issued on 30th December 2015*
[7] *Notification (G.S.R 817(E)) dated 28th August 2018 issued by the Ministry of Health and Family Welfare*

Prohibitions Proposed on E-Pharmacies

- Ban on sale or distribution of:
  - Narcotic and psychotropic substances (as per NDPS Act, 1985).
  - Tranquilisers and Schedule X drugs.
  - Ban on advertising drugs via any media (TV, radio, internet, print, etc.)..

to strictly prohibit the e-pharmacies from (a) engaging in the business of distribution or sale, stock, exhibition, or offer for sale of drugs covered under the categories of the narcotic and psychotropic as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985, tranquilisers and drugs as specified in Schedule X of Drugs and Cosmetics Rules, 1945, and (b) advertising any drugs on radio, television, internet, print, or any other media. Similar provisions as contained in the existing Drugs and Cosmetics Rules, 1945, with respect to suspension or cancellation of registration, complaint redressal mechanism, etc., are sought to be made applicable to e-pharmacies. The 2018 Draft Amendment has not been notified and is yet to come into force.

A Writ Petition was filed before the Madras High Court[8] by the Tamil Nadu Chemists and Druggists Association seeking directions for blocking the links of all e-pharmacy websites that are carrying on online sale of drugs listed in Schedule H (prescription drugs), H1 (high-risk prescription drugs) and Schedule X (drugs with high potential for abuse and addiction) in violation of Rules 65 (which stipulates the conditions for granting licences for drugs other than homeopathic medicines) and 97 (which provides the manner of labelling of drugs other than homeopathic medicines) of the Drugs and Cosmetics Rules, 1945. By way of an Order dated December 17, 2018, the Madras High Court while directing the Central Government to notify the 2018 Draft Amendment at the earliest in public interest, also restrained the e-pharmacies from proceeding with the online sale of drugs. However, the Court vacated the injunction on an appeal filed by the e-pharmacies[9] and allowed the online sale of drugs subject to the condition that it be carried out only through licenced druggists and chemists.[10]

Similar Writ Petitions filed before the Delhi High Court[11] led to an order restraining the e-pharmacies from the online sale of drugs without a licence. During a hearing before the Delhi High Court on March 4, 2025, the Court directed the Ministry of Health and Family Welfare to frame a policy on the online sale of drugs in terms of the 2018 Amendment within four months, i.e., by July 2025. The Madras High Court has disposed of this appeal filed by the e-pharmacies with a direction to the Central Government and the Central Drugs

[8] *The Tamil Nadu Chemists and Druggists Association v Union of India, 2018 SCC OnLine Mad 3515*
[9] *M/s. Practo Technologies Pvt. Ltd. v. The Tamil Nadu Chemists and Druggists Association, Writ Appeal No. 2807 of 2018 (Madras High Court)*
[10] *M/s. Practo Technologies Pvt. Ltd. V. The Tamil Nadu Chemists and Druggists Association, Writ Appeal No. 2807 of 2018, Order dated June 25, 2024 (Madras High Court)*
[11] *Zaheer Ahmed v Union of India, W.P(C) No. 11711/2018, Order dated March 4, 2024 (Delhi High Court)*

Standard Control Organization to expedite and finalise the policy governing the online sale of drugs and notify the same. However, no such policy or notification related to the online sale of drugs by e-pharmacies has been issued as of date.

Separately, the Ministry of Health and Family Welfare has published the Draft Drugs, Medical Devices and Cosmetics Bill, 2022, seeking comments from the public. The Bill intends to serve as a comprehensive statute for import, manufacture, distribution, and sale of drugs, medical devices and cosmetics and carve out specific provisions for online pharmacies and clinical trials. If and when enacted, it would replace the Act, which was a pre-independence legalisation.

Meaning of the terms "Drug" and "Cosmetic" under the Act

1. **Drug:** The meaning and scope of the term "drug", as defined under Section 3(b) of the Act, is expansive, encompassing drugs as understood in normal parlance; medicines intended for internal or external use in human beings or animals; substances intended for use in diagnosis, treatment, mitigation, or prevention of any disease or disorder in human beings or animals; substances (other than food) intended to affect the structure or any function of the human body; substances intended for use in the destruction of vermin or insects causing diseases in human beings or animals; and substances intended for use as components of a drug, including empty gelatin capsules and medical devices. The Act empowers the Central Government to expand via notifications the ambit of substances and medical devices that can be termed as drugs under the Act. By invoking this power, the Central Government has notified contraceptives, disinfectants, cardiac stents, drug-eluting stents, nebuliser, blood pressure-monitoring device, digital thermometer, glucometer, etc. as drugs under the Act. Through a subsequent notification,[12] the Central Government has brought *all* medical devices within the ambit of Section 3(b)(iv) of the Act. These devices are now governed by the Medical Devices Rules, 2017, which impose quality control

A "**drug**" (as defined under Section 3(b) of the Act) includes:

- any substance or preparation intended for internal or external use in the diagnosis, treatment, mitigation, or prevention of disease or disorder in humans or animals;
- substances (excluding food) that affect the structure or function of the human body;
- items used to destroy disease-causing vermin or insects; and
- components of drugs such as empty gelatin capsules and medical devices.

[12] *Ministry of Health and Family Welfare, Notification No. S.O.648(E) dated February 11, 2020*

requirements. The Act also draws a distinction between allopathic drugs and traditional systems of medicine such as Ayurveda, Siddha, and Unani.

- ***Insight:*** The Courts[13] have consistently applied various tests to expand the scope and meaning of the definition of drugs under the Act. The most common test for determining the product as a drug is the Twin Test, comprising the common parlance test / user test, which evaluates (i) how the product is commonly understood by ordinary consumers and (ii) whether the ingredients used for the manufacturing of the product are described in medical literature as necessary for curing / healing. The Supreme Court observed that if a product is used for treating a particular ailment and is discontinued after the ailment is cured, it is typically understood as a medicine. The Supreme Court[14] held that "Medical Oxygen IP" and "Nitrous Oxide IP" qualify as "drugs" under Section 3(b)(i) of the Act as they are used in the treatment and mitigation of diseases. The Court applied the "user test" while observing that both products are recognised in medical practice as essential for the treatment or mitigation of diseases and often prescribed or administered by medical practitioners.

The Supreme Court has observed that any product used for treating a particular ailment and discontinued after the ailment is cured is regarded as a medicine.

- Another test determined by the Supreme Court was the primary function test, which distinguishes products used primarily for cure (medicament) from those meant for care (cosmetic). On applying this test, it can be ascertained that the cosmetic products are used to enhance or improve a person's appearance or beauty, whereas medicinal products are used to treat or cure some medical condition. A product used mainly for curing or treating ailments or diseases and contains curative ingredients even in small quantities is to be branded as a medicament.[15]

- The Supreme Court[16] interpreted Section 3(b) of the Act and held that "drug" includes not just medicines but also "substances intended to be used for or in the treatment, mitigation, or prevention of disease in human beings or animals." The term "substances" under the Act refers to things that may not be medicines in the strict sense but are used for treatment. While interpreting the term "substances" to qualify as drugs under the Act, the Court held that it should be ascertained whether an item proposed to be qualified as drugs under the Act is a substance and whether it is used for treatment. Applying these principles, the Supreme Court expanded the scope of "substances" under the Act to include absorbent cotton wool, roller

[13] *Puma Ayurvedic Herbal (P) Ltd. v. CCE, (2006) 3 SCC 266*
[14] *State of Andhra Pradesh v. M/s Linde India Ltd., (2020) 16 SCC 335*
[15] *CCE v. Ciens Laboratories, (2013) 14 SCC 133*
[16] *Chimanlal Jagjivan Das Sheth v. State of Maharashtra, 1962 SCC OnLine SC 16*

bandages, and gauze because these are used for surgical dressing, sterilised for antiseptic use, and are vital aids in medical and surgical treatment.

- Similarly, Himachal Pradesh High Court held that bleaching powder, used in sanitation and disease control, qualifies as a "drug" under Section 3(b)(i) of the Act.[17] Other inclusions under this category are water used to dissolve medicines for administration into the human body via injection[18] and blood when used for treatment or prevention of any disease or disorder in human beings since blood drawn for medical treatment is sold or distributed as a "drug" to patients in need, especially for transfusions during surgeries or to treat a disease. This made it necessary to regularise the drawing of blood to prevent a health hazard.[19] Further, commonly used products like Boroline,[20] which are generally used for treating minor wounds and skin ailments, are also classified as drugs under the Act.

- The definition of a drug is not rigidly tied to its inclusion in pharmacopoeia, in that a product does not automatically become a drug because it appears in the *Indian Pharmacopoeia* or *British Pharmacopoeia*. The Bombay High Court has held that whether an item is a drug is a question of fact, determined by its intended use. Thus, the focus remains on not only what a product is but how it is marketed and used.[21]

2. **Cosmetic:** The term "cosmetic" as defined in Section 3(aaa) of the Act was inserted through an amendment in 1982. It refers to any article intended for application on the human body for beautifying, cleansing, or altering appearance, such as *gandh*, nail polish,[22] talcum powder, "*gudakhu*",[23] and lipsticks. However, since culturally nuanced interpretations exist as well, the principles of common parlance test and the primary function test to classify items as drugs under the Act are often used to even classify cosmetics under the Act.

A "**cosmetic**" (as defined under Section 3(aaa) of the Act) is any article intended to be applied to the human body for the purpose of beautifying, cleansing, or altering appearance.

- ***Insight:*** The Madras High Court[24] dealt with the case of "*kumkum*", traditionally used by Hindu married women. The Court held that while the conventional red or

[17] *Durga Das Bansal v. State of Himachal Pradesh, 1982 SCC OnLine HP 46*
[18] *Ram Chandra Sundarka v. State of West Bengal, 1971 SCC OnLine Cal 135*
[19] *Subodh S. Shah v. Director, Food and Drug Control Office, Ahmedabad, AIR 1997 Guj 83*
[20] *Abdul Moid v. State, 1976 SCC OnLine All 424*
[21] *State of Maharashtra v. Ramesh Rastogi, 1972 Mah LJ Note 22*
[22] *State of Mahrashtra v. Zahid Hussain Kikabhai, 1975 Mah LJ 455*
[23] *Gopilal Agarwal v State of Orissa, AIR 1973 Ori 15*
[24] *Y.V. Seshachalam & Co. v. Secretary to Government of Tamil Nadu, 1977 SCC OnLine Mad 337*

yellow *kumkum* used as a religious mark does not fall within the definition of "cosmetic" under the Act, when manufactured in various shades to match the colour of the clothing and used for enhancing the appearance of the person wearing it, *kumkum* loses its religious character and becomes a "cosmetic" under the Act.

- The Supreme Court held that products cannot be classified as cosmetics solely on the basis of their outward packing. Even if the packaging suggests that the product is a "cosmetic", it could still be determined and treated as a "medicine" based on its composition.[25]

Officers under the Act

Under the Act, the prosecution unfolds with the Drug Inspector (*Section 21*) inspecting the premises and collecting the sample of the drug or cosmetic to examine the quality *(Section 22)*. The Government Analyst then analyses and tests these samples and submits a report in triplicate is to the Drug Inspector *(Section 25)*. The findings of the report are considered conclusive upon receipt, unless the person from whom the sample was taken or the person notified as manufacturer under Section 18A of the Act intends to adduce evidence contradicting the report and notifies the same in writing to the Inspector or the Court (Sessions Court or a Court of Metropolitan Magistrate or Judicial Magistrate of the first class depending on the nature of the violation under the Act) before which any proceedings in respect of the sample are pending. If a person has notified the intention of challenging the report, the appropriate Court may cause the sample to be sent for analysis to the Central Drugs Laboratory, whose report shall be conclusive evidence of the facts stated therein. Basis the outcome of the testing, the Drug Inspector may initiate criminal proceedings before the Sessions Court or a Court of Metropolitan Magistrate or Judicial Magistrate of the first class depending on the contravention of the provisions under Chapter III, IV, IVA, or V of the Act.

The Act envisions enforcement through a structured network of authorities functioning under the aegis of the Act, including the following:

1. ***Drug Inspectors:*** Section 22 of the Act vests Drug Inspectors with powers including search and seizure, inspection of

Officers under the Act

Drug Inspectors

- Empowered by: Section 22
- Key Powers:
  - Search and seizure
  - Inspection of premises
  - Sampling and record examination
  - Regulating manufacture, sale, distribution, and quality of drugs
- Legal Boundaries:
  - Must follow procedural stipulations
  - Missteps or overreach can vitiate prosecutions

[25] *Meghdoot Gramodyog Sewa Sansthan v. CCE, (2005) 4 SCC 15*

premises, taking samples, and examining records for the purpose of regulating the manufacture, sale, distribution, and quality of drugs. The Drug Inspectors are required to exercise their powers and follow procedural stipulations as per law. Missteps, overreach, or non-compliance have led to the vitiation of prosecutions initiated under the Act.

- ***Insight:*** The Supreme Court has held that the power to regulate, restrict, or prohibit the manufacture or sale of a drug lies exclusively with the Central Government under the Act. In one case,[26] it was clarified that although Inspectors have certain procedural and enforcement powers under Section 22 of the Act, including inspecting premises, taking samples, and seizing drugs or cosmetics suspected to be in violation of the provisions of the Act, they cannot unilaterally impose new prohibitions, classify a duly licenced drug as contraband, or ban any drug. The Inspector's authority is limited to enforcing existing law and reporting statutory violations and not creating new bans or restrictions. Any such restriction is valid only if the Central Government notifies it through the process established under the Act.

- ***Insight:*** The correctness or conclusiveness of the Government Analyst's report as evidence under Section 25 of the Act also depends on the proper discharge of the duties by the Inspector while collecting the samples for analysis. The Supreme Court[27] has clarified that the Inspector is required to distribute parts of the sample as follows: one to the person from whom the sample was actually taken, another to the Government Analyst, a third to the Court, and another (if applicable) to the person disclosed as manufacturer under Section 18A of the Act *(Section 23(4))*. The Inspectors are not mandated to provide a sample directly to the manufacturer when the sample is taken from a retailer or distributor unless the manufacturer is the direct subject of the sample collection. The Supreme Court has time and again reiterated that the Inspectors' powers and duties are to be carried out as per the statutory protocol.

- The Allahabad High Court acquitted the applicant convicted under Section 18 of the Act (which prohibits the manufacture, sale, etc., of misbranded, adulterated, or spurious drugs) as the Municipal Medical Officer of Health, who took the sample from the applicant's shop, did not have the required authority under the Act to take and send drug samples for testing. This vitiated the prosecution arising from collection of such a sample. In this case, the Municipal Medical Officer of Health was appointed as an Inspector only to inspect retail shops and did not have the authority to procure and send samples for analysis. Additionally, the Government Analyst's report was ruled inadmissible as evidence because the officer taking the samples was not statutorily empowered and the report was not in the prescribed

[26] *M/s. Bhagwati Medical Hall v. Central Drug Standard Control Organization, SLP (C) Nos. 22833-22834 of 2022 Order dated December 19, 2024 (Supreme Court)*
[27] *Amery Pharmaceuticals v. State of Rajasthan, (2001) 4 SCC 382*

form as it lacked the full disclosure of the protocols of tests the Government Analyst had applied,

- ***Insight:*** Judicial debate persists on whether the Drug Inspector is akin to a police officer. The Supreme Court[28] has held that a Drug Inspector is not a "police officer" for the purposes of Section 25 of the Evidence Act, 1872 (which provides that any statement or confession made by an accused person to a police officer cannot be used as evidence against that person in the Court of law) or the scheme of the Code of Criminal Procedure, 1973. His investigative powers are circumscribed by the statute and do not extend to arrest or submitting charge-sheets in criminal courts as police officers do. Similarly, the Delhi High Court[29] has held that while the Inspectors exercise investigative powers similar to a police officer in certain aspects, they are not considered as "police officers" within the meaning of Section 25 of the Indian Evidence Act, 1872. What follows is that Section 495(4) of Code of Criminal Procedure, 1973, which prohibits a police officer who has taken part in the investigation from conducting the prosecution, shall not be strictly applicable to a Drug Inspector. However, the Delhi High Court has criticised the practice of allowing a Drug Inspector who was involved as investigator to conduct prosecution in the case, since the Drug Inspector would also be a witness. Though not legally barred, it was considered "not healthy" to allow a Drug Inspector to conduct prosecution of such cases. The Court recommended that the prosecuting officer be distinct from the investigating Inspector to uphold the integrity of the judicial process.

2. ***Government Analyst:*** The Government Analyst appointed under Section 20 of the Act is a statutory authority empowered under the Act to conduct tests or analysis of drug/cosmetics samples collected by the Inspectors. Section 23 of the Act mandates specific procedural safeguards during seizure and sampling, ensuring the integrity of the sample and fairness in investigation. Rule 45 of the Drugs and Cosmetic Rules, 1945, requires the Government Analyst to furnish to the Inspector the report of the analysis of the sample drugs or cosmetics submitted by the Inspector or other persons under Chapter IV of the Act within 60 days of receipt of the sample. The Government can extend this period upon a request from the Government Analyst seeking extension of time and providing specific reasons for the delay in adhering to the timeline set out in the Rule. Delay in

Officers under the Act

Government Analyst

- Appointed under: Section 20
- Role: Conduct tests/analysis of drug or cosmetic samples
- Procedural Safeguards:
  - Governed by Section 23 and Rules 45 & 46 of the Drugs and Cosmetics Rules, 1945
  - Must ensure sample integrity and fair investigation

[28] *Union of India v. Ashok Kumar Sharma, (2021) 12 SCC 674*
[29] *Mohan Lal Gupta v. State, 1972 SCC OnLine Del 201*

providing the report may result in the vitiation of the proceedings instituted pursuant to the report of the Government Analyst.[30] Rule 46 requires the Government Analyst to submit a report in triplicate to the Inspector detailing the results of the analysis of the sample with the full protocols of the tests or analysis applied. Non-disclosure of the protocols of the tests applied during analysis of the sample can render the report inadmissible in evidence.[31] Upon receipt of such a report by the Inspector, one copy of the report is required to be supplied to the person from whom the sample was taken, another to the person whose particulars have been disclosed under Section 18A as the manufacturer (this is applicable in cases where the sample is taken directly from a person who is not a manufacturer), and a third is required to be retained by the Inspector for prosecution, if any, in respect of the sample *(Section 25(2))*. Section 25(3) of the Act makes the report of the Government Analyst conclusive evidence of the facts stated therein, unless the accused notifies the Inspector or Court (Sessions Court or a Court of Metropolitan Magistrate or a Judicial Magistrate of the first class depending on the nature of the violation under the Act) before which any proceedings in respect of the sample are pending within 28 days of receipt of the report that they intend to controvert the report of the Analyst by adducing contrary evidence.[32] Failure to supply the copy of the Analyst's report as set out in Section 25(2) of the Act violates the statutory right of the party to contest the report's findings, rendering any conviction unsustainable.[33] This valuable right, if denied, vitiates the prosecution. If the Government Analyst's report is sought to be controverted by a party under Section 25(3) of the Act, the Court may, on its own motion or at its discretion, at the request of the party send the retained sample for further testing and analysis to the Central Drugs Laboratory and the resultant report from the said laboratory will become final and conclusive. A delay in filing a complaint under the Act resulting in there being no opportunity provided to the accused for retesting before the sample's expiry under Section 25(3) and 25(4) of the Act vitiates the entire prosecution.[34]

- Reporting Requirements

Rule 45:
- Submit analysis report within 60 days
- Extension allowed with valid reasons
- Delay may vitiate proceedings

Rule 46:
- Report in triplicate with full test protocols
- Non-disclosure of protocols renders report inadmissible

- ***Insight:*** The Government Analyst is required to provide the reports to the entity from whom the sample was taken. If, in case the abovementioned entity is not the

[30] *Swapnil v. State of Maharashtra, 2024 SCC OnLine Bom 2074*
[31] *Raj Kishan v. State, 1959 SCC OnLine All 152*
[32] *State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343*
[33] *Drugs Inspector, CDSCO v. Modern Drugs, 1981 SCC OnLine Mad 235*
[34] *Medicamen Biotech v. drug Inspector, (2008) 7 SCC 196; Embiotic Laboratories (P) Ltd. v. State of Tamil Nadu 2015 SCC OnLine Mad 9818; Cipla Ltd v. State of J&K, Cr MC No. 614 of 2016 Order dated September 30, 2022 (Jammu & Kashmir and Ladakh High Court)*

manufacturer, then Section 18A of the Act requires disclosure of the manufacturer's identity by the person from whom the drug was seized. and upon such disclosure, to provide a portion of the sample and the Government Analyst's report in terms of Section 23(4)(iii) and 25(2) of the Act, respectively, to the said manufacturer. The purpose of Section 18A is to disclose the name, address, and other particulars of the manufacturer of the drug in question and to ensure that the manufacturer is given a fair opportunity to exercise rights under the Act, including the right to defend that the drug manufactured(from which the Inspector drew the sample for testing) did not lack in the requisite standard of quality prescribed under the Act.[35]

- Distribution of Report **(Section 25(2))**
  - One copy each to:
    - Person from whom sample was taken
    - Manufacturer (if applicable under Section 18A)
    - Retained by Inspector for prosecution Legal Implications

Section 25(3):
- Report is conclusive unless contested within 28 days
- Failure to supply report violates statutory rights
- Denial of right to contest invalidates conviction

Section 25(4):
- Court may order retesting by Central Drugs Laboratory
- Resultant report is final and binding
- Delay in complaint filing that prevents retesting before sample expiry vitiates prosecutiony

- ***Insight:*** In cases where the samples were not taken directly from the manufacturer but from the retailer of distributor, the manufacturer may not be a party accused to the criminal proceedings initiated by the Drugs Inspector. There may also be cases where the details of the manufacturer are not disclosed by the parties in terms of Section 18A of the Act, resulting in the manufacturer not being made a party to the criminal proceedings and consequently not being supplied with the sample and the Government Analyst's report, as stipulated in Section 25 of the Act. In such a situation, the manufacturer may also miss the 28-day window to adduce evidence contradicting the findings of the Government Analyst's report. However, the mere non-impleadment of the manufacturer as party defendant to the criminal proceedings initiated by the Inspector does not bar the manufacturer from being impleaded subsequently as an accused in the proceedings, considering the gravity of the offence. Particularly for such situations, Section 32A of the Act empowers the Court to implead the manufacturer in a trial even if the manufacturer was not initially a defendant in the case, if the Court is satisfied by the evidence adduced that the manufacturer is also concerned in the offence. The Supreme Court,[36] while adjudicating the rights of the manufacturer challenging the

[35] *M. K. Hameid v State through K. T. Raghu Kumar, Drug Inspector, 2023 SCC OnLine Del 5520*
[36] *Amery Pharmaceuticals v. State of Rajasthan, (2001) 4 SCC 382*

Government Analyst's report, rejected the artificial distinction between a manufacturer arraigned as an accused in the initial stage of the prosecution and one arraigned during the trial under Section 32A of the Act. It held that the right to challenge the Government Analyst's report under Section 25 should apply equally to both the circumstances. The Supreme Court emphasised that denying the report to one category of manufacturers who are impleaded at the stage of trial based on a procedural technicality would jeopardise public health and thwart the object of the statute. Hence, the Courts are required to interpret the law in a manner that ensures the accused's right to a fair defence while preserving the public interest. In this case, the Supreme Court held that the Inspector was not legally obliged to give a sample or report directly to the manufacturer if the sample was not taken from the manufacturer. However, if the manufacturer does not receive the sample or report, their right to challenge the Government Analyst's report is not extinguished. The manufacturer may request the Court to send the sample retained with the Court to the Central Drugs Laboratory for further testing, as allowed under Section 25(4) of the Act.

- In another case, the Supreme Court[37] held that in the event the manufacturer (whose details are disclosed in Section 18A of the Act) is not supplied with a sample under Section 23(4)(iii) of the Act but only with the report of the Government Analyst, the valuable right of the manufacturer to contest the findings of the Government Analyst's report was held to be denied and the prosecution based on the report was liable to be quashed.

- ***Insight:*** A valuable right is bestowed under Section 25(4) of the Act upon a person sought to be prosecuted under the Act to have the retained sample, which is similar to the sample assessed by the Government Analyst being tested by the Central Drugs Laboratory. However, these right holds meaning only if the retained sample is tested by the Central Drugs Laboratory before its deterioration or expiration period. If, the sample cannot be retested in a meaningful manner owing to it being deteriorated or expired due to unexplained or unjustified delay by the authorities, then any prosecution or penalty based on such testing cannot be sustained in law. The Supreme Court has often underscored the critical importance of timely testing of drug samples under the Act holding that unexplained and inordinate delay attributable to the authorities can invalidate any penalty or prosecution based on such delayed analysis. In one case it was noted that the delay in testing extending to over eight months beyond the product's shelf life frustrated the statutory right of the party under Section 25 of the Act to seek reanalysis by the Central Drugs Laboratory. In this case, both the initial and the appellate testing was delayed owing

[37] *Laborate Pharmaceuticals India Ltd. v. State of Tamil Nadu, (2018) 15 SCC 93*

to the inaction of the authorities, resulting in the quashing of the prosecution initiated by the inspector pursuant to such delayed testing.[38]

Framework of actions that can be taken under the Act

The actions that can be taken under the Act are as follows:

(a) Imprisonment and / or fine as prescribed under the Act for various offences including manufacture for sale, distribution, sale or stocking or exhibiting of adulterated or spurious drugs *(Section 27)*; manufacture for sale, distribution, sale or stocking or exhibiting of adulterated or spurious cosmetics *(Section 27A)*; non-disclosure of details of the manufacturer from whom the drug or cosmetic in question was acquired *(Section 28)*; failure to maintain records, registers, or documents as prescribed under the Act *(Section 28A)*; manufacture for sale, sale or distribution of any drugs or cosmetics prohibited by the Central Government *(Section 28B)*.

(b) Penalty as prescribed under the Act for misuse of reports of a test or analysis of the Central Drugs Laboratory or Government Analyst for the purpose of advertisement of any drugs or cosmetics *(Section 29)*.

(c) Confiscation of the stock of drugs or cosmetics of a person convicted under the Chapter IV of the Act for the contravention of any provisions thereof *(Section 31)*. Additionally, if the person is convicted for manufacturing any drug deemed to be misbranded *(Section 17),* adulterated *(Section 17A)*, or spurious *(Section 17B),* then confiscation can also extend to machinery, implements, or vehicles used in the commission of such offences.

Suspension and Cancellation of Licence under the Act and Drugs and Cosmetics Rules, 1945

The power to suspend or cancel a licence issued under the Drugs and Cosmetics Rules, 1945 for non-compliance with the conditions of the licence or with any provisions of the Act or rules thereunder is bestowed upon the Licensing Authority or the Central License Approving Authority. In those cases governing violation of licence issued for the sale of drugs and manufacture of cosmetics for sale or for distribution, the Licensing Authority has the statutory power to suspend or cancel a licence *(Rule 66, 67H, 85I, 122O 143 and 159)*. In the cases governing violation of licence issued for manufacture for sale or for distribution of drugs (other than homeopathic drugs), the Central License Approving Authority has the statutory power to suspend or cancel a licence *(Rule 85)*. The Licensing Authority and the Central License Approving Authority have the power to cancel a licence,

[38] *Medipol Pharmaceutical India Pvt. Ltd. v. Post Graduate Institute of Medical Education & Research (2021) 11 SCC 339*

either wholly or in relation to some violation-related substances, if the licensee does not comply with any of the conditions of the licence or the provisions of the Act or the Drugs and Cosmetics Rules, 1945. If such an order of suspension or cancellation of a licence is passed by an authority not competent to pass such an order (viz., Drugs Control Officer), the order is liable to be quashed.[39] An aggrieved party may prefer an appeal against the order of suspension of cancellation of licence before the State Government within a period of three months from the date of the order.

- ***Insight:*** It is a statutory requirement to pass a reasoned order while suspending or cancelling a licence. While doing so, there is a pre-requisite to issue notice to the licence holder and provide the licence holder an opportunity to show cause and establish why its licence should not be suspended or cancelled. While the Drugs and Cosmetics Rules, 1945, do not expressly require an opportunity of *personal hearing*, judicial pronouncements have emphasised the need to follow the principles of natural justice before such a decision is taken against a licence holder. However, in cases where the party does not deny the allegations in the show cause notice in the reply, the order cancelling the licence cannot be attacked on the ground that it was not a speaking order.[40] However, the licensee not being granted an adequate opportunity to explain or defend the allegations contained in the show cause notice would render the action of suspension or cancellation of its licence invalid.[41]

- In a case before the Rajasthan High Court,[42] a licence granted to a licensee for manufacture for sale of ayurvedic drug was cancelled by the licensing authority solely on the basis of a direction issued by the State Government (which is also the appellate authority in respect of cancellation of licences by the licensing authority) for such cancellation. As the licensing authority had not met the prior requirement of issuing a show cause notice before issuing the order of cancellation, the Court set aside the order of cancellation of licence because it was passed in violation of the principles of natural justice and without application of mind. The plea of the licensing authority that the licensee had not availed the remedy of statutory appeal before the State Government and had instead directly approached the High Court was also rejected on the ground that no useful purpose would have been served in the facts of the case if an appeal had been preferred before the State Government since its mind was already made up against the licensee.

- ***Insight:*** The Courts have held that even though the rules provide for the suspension or cancellation of a "*licence*", the same shall not be interpreted to restrict its meaning to a single licence but rather it covers any licence issued under Part VI of the Drugs and Cosmetics Rules, 1945 (which pertains to sale of drugs other than homoeopathic

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[39] *Riyaz Ahmad Mugloo v Union Territory of Jammu & Kashmir, WP (C) No. 1444 of 2022, Order dated December 16, 2024 (Jammu & Kashmir and Ladakh High Court)*
[40] *Bishamber Nath v. Drugs Licensing Authority, 1972 SCC OnLine Del 217*
[41] *P.C. Guha & Sons v. State of West Bengal, 2004 SCC OnLine Cal 492; North Bihar Agency v. State, (1981) 3 SCC 131 : 1981 SCC (Cri) 651*
[42] *Goa Antibiotics v State of Rajasthan, 2008 SCC OnLine Raj 257*

medicines), thereby allowing for the cancellation of multiple licences if warranted under law.[43]

Chapter IVA also contains similar provisions for ayurvedic, siddha, and unani drugs.

Power of the Courts to take cognizance of an offence under the Act

As per Section 32(1) of the Act, the prosecution for contravention of any provisions under Chapters IV (regulating the manufacture, sale, and distribution of drugs and cosmetics) and IVA (regulating the manufacture, sale, and distribution of ayurvedic, siddha, and unani drugs) shall be instituted only by the following persons prescribed under the Act:

(a) inspector,
(b) any gazetted officer of the Central Government or the State Government authorised in writing in this behalf,
(c) person aggrieved, or
(d) a recognised consumer association irrespective of whether such person is a member of that association or not.

- ***Insight:*** Police officers have no power to register an FIR or investigate offences under Chapter IV (regulating the manufacture, sale, and distribution of drugs and cosmetics) of the Act. In the event a complaint relates to an offence under any other law in addition to an offence under Chapter IV of the Act, the police officer may investigate and prosecute under the other relevant law but not for offences held to be cognizable under Chapter IV of the Act. The procedure under Section 32 of the Act is exclusive and overrides the general provisions of Code of Criminal Procedure, 1973, for the cognizable offences under the Act.

- The Supreme Court held that a prosecution for cognizable offences under the Act initiated solely by a police officer based on the FIR they filed was not legally valid[44] in light of the express provisions of Section 32(1) of the Act. It also held that the Inspector is empowered to arrest a person in connection with the offences under the Act, however, such power is not conferred on a police officer. The role of the police officer is limited to assisting the Inspector if facing resistance to arrest.

- In a case where the complaint was filed by a Drug Inspector and was accompanied by a police charge sheet, the Bombay High Court[45] held that it would not amount to vitiation of the prosecution under Section 32 of the Act as the origin of the prosecution remained with the designated authority under the Act, i.e., the Drug Inspector.

Section 32(2) of the Act provides that only a Court of Sessions can try the offences under

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[43] *Bishamber Nath v. Drugs Licensing Authority, 1972 SCC OnLine Del 217*
[44] *Union of India v Ashok Kumar Sharma, (2021) 12 SCC 674*
[45] *State v. Chunilal Vallabhji Gandhi, 1958 SCC OnLine Bom 243.*

Chapter IV of the Act. Section 36(AB) provides for designating one or more Courts of Session as a Special Court under the Act for trying offences relating to adulterated drugs or spurious drugs punishable under Section 13(a) (which provides for imprisonment for a term that may extend to 3 years and fine up to INR 5,000), Section 13(b) (which provides for imprisonment for a term that may extend to six months and/or fine up to INR 500), Section 27(a) (which provides for punishment of a minimum term of 10 years but may extend to imprisonment for life and fine of INR 10,00,000 or three times the value of the drugs confiscated), Section 27(c) (which provides for punishment of a minimum term of seven years that may extend to imprisonment for life and fine of INR 3,00,000 or three times the value of the drugs confiscated), Section 28 (which provides for punishment of imprisonment for a term that may extend to one year and / or with fine of not less than INR 20,000), Section 28A (which provides for punishment up to one year imprisonment and/or fine up to INR 20,000), Section 28B (which provides for punishment up to three year imprisonment and fine up to INR 5,000) and Section 30(1)(b) (which provides for punishment for a minimum term of ten years and may extend to imprisonment for life and fine of not less than INR 3,00,000), and other offences relating to adulterated drugs or spurious drugs under the Act. Accordingly, a complaint in respect of the aforementioned cognizable offence under the Act can be filed by the specified persons under Section 32(1) directly before the Special Court (Court of Sessions) instead of first approaching the Court of Magistrate. The offences under the remaining chapters, *viz* Chapters III (provisions relating to import of prohibited, adulterated, spurious, or misbranded drugs or cosmetics) and IVA (provisions regulating the manufacture for sale or for distribution, selling, or stocking or exhibiting or offering for sale or distributing, ayurvedic, siddha, and unani drugs) are to be tried by the Metropolitan Magistrate or Judicial Magistrate of the first class *(Sections 15 and 33M)*. An appeal against the order passed by the Special Court shall lie before the High Court *(Section 36AE)*. In cases involving complaints initiated under the Act, appeals against orders of acquittal by a Court of Magistrate can only be preferred to the High Court with its special leave under Section 378(4) Code of Criminal Procedure, 1973, and not to the Sessions Court.[46]

- ***Insight:*** Section 36AD of the Act makes the provisions of the Code of Criminal Procedure, 1973, applicable to proceedings before the Special Court. Section 193 of Code of Criminal Procedure, 1973, prohibits the Court of Sessions from taking cognizance of any offence as a Court of Original Jurisdiction unless the case has been committed to it by a Court of Magistrate under the Code of Criminal Procedure, 1973. However, since Section 32 of the Act allows specified persons to file a complaint directly before the Court of Sessions instead of first approaching the Court of Magistrate, the provision can be said to be in conflict with Section 193 of Code of Criminal Procedure, 1973. Notably, the Act does not contain an express provision conferring power upon the Court of Sessions to directly take cognizance of the complaint without an order of committal by the Court of Magistrate.[47] Such provisions

[46] *Subhash Chand v State (Delhi Administration), (2013) 2 SCC 17*
[47] *Padma Pharmaceuticals v the State through Drug Inspector, Cr. Revision Petition No. 200077 of 2018, Order dated February 20,*

conferring power upon the Court of Sessions to directly take cognizance of offences without an order of committal by the Court of Magistrate is provided in other special legalisations such as Scheduled Castes and the Scheduled Tribes (Prevention of Atrocities) Act, 1989, and the Prevention of Corruption Act, 1988. Keeping the above provisions in mind, the Karnataka High Court[48] held that a Magistrate does not have the jurisdiction to try a proceeding arising out of a complaint filed by a competent officer under Section 32(1) of the Act for offences punishable under Chapter IV of the Act. In such cases, it was held that the Magistrate is required to commit the matter concerning offences under Chapter IV of the Act to the Court of Sessions for trial instead of adjudicating the matter directly.

Another critical aspect relating to the validity of prosecution pertains to the requirement of sanction from the Central Government or the State Government in certain cases. Specifically, for offences involving ayurvedic, siddha, or unani drugs under Chapter IVA of the Act, Section 33M requires prior sanction from the Central or State Government before instituting any prosecution. Any criminal prosecution initiated for offences under Chapter IVA of the Act without sanction under Section 33M is liable to be quashed.[49]

Offences under the Act by companies

The Act provides for offences committed by juristic entities such as companies, firms, or associations of individuals. Codified under Section 34 of the Act, in such cases, the law provides a mechanism for vicarious liability[50] to be imposed on individuals responsible for

Section 34: Companies, firms, and associations of individuals responsible for the conduct of a company's business at the time of the offence are liable.

Section 18(a)(i): Prohibits manufacture/sale of misbranded, adulterated, or spurious drugs/cosmetics.

Section 27(d): Prescribes punishment (1–2 years imprisonment + fine ₹20,000) for contraventions under Chapter IV.

Scope of Individual Liability

- Only those in actual control of day-to-day operations are liable.
- Mere designation (e.g., director or partner) is insufficient.
- Complaints must include specific factual averments about the individual's role. drugs/cosmetics.

2025 (Karnataka High Court); Kalpataru Medicos v Food and Drugs Administration, M. Cr. C. No. 11940 of 2016, Order dated January 10, 2017 (Madhya Pradesh High Court)

[48] *Padma Pharmaceuticals v the State through Drug Inspector, Cr. Revision Petition No. 200077 of 2018, Order dated February 20, 2025 (Karnataka High Court)*

[49] *P.S. Singarayan v. State by Drugs Inspector, 2002 SCC OnLine Mad 888*

[50] *State of Haryana v. Brij Lal Mittal, (1998) 5 SCC 343*

the conduct of the business of such entities at the time the offence was committed.

- ***Insight:*** The Act contains penal provisions for contraventions, with liability in certain cases extending to directors and officers of companies under Section 34 of the Act. However, the Courts have clarified the scope of such liability and the circumstances under which complaints under the Act may be quashed. The Supreme Court interpreted the phrase "*a person in charge of and responsible to the company for the conduct of the business*" appearing in Section 34 of the Act to mean that such a person must be in overall control of the day-to-day affairs of the company or firm. Mere designation as a director or partner does not *ipso facto* establish that the individual was in charge of the business when the offence took place. Complaints must show that the individual had actual control and responsibility for the conduct of the business at the material time[51] and contain specific, factual averments about the role of such individuals in the company's business.[52]

- The Delhi High Court[53] quashed the proceedings initiated against the directors of the manufacturer, Cipla Limited, by the Metropolitan Magistrate under Section 18(a)(i) (which prohibits the manufacture, sale, etc., of misbranded, adulterated, or spurious drugs or cosmetics) and Section 27(d) (which prescribes punishment of imprisonment for a minimum term of one year that may extend to two years and fine of minimum INR 20,000 for the manufacture, sale, etc., of drugs in contravention of any provision of Chapter IV) of the Act, holding that senior officers of a company are not automatically liable for offences under the Act in the absence of clear evidence showing their responsibility for the company's operations at the time of the alleged offence. In this case, it was established that a power of attorney was executed in favour of another individual in charge of the conduct of the day-to-day business of Cipla Limited and accordingly he alone was held liable to be prosecuted under Section 34 of the Act and not the directors of Cipla Limited who were not in charge of the conduct of the day-to-day business.

- The High Court of Jammu & Kashmir and Ladakh[54] rejected the contention of the company that the proceedings initiated against it for offences under Sections 18(a)(i) and 27(d) of the Act should be quashed for non-joinder of the directors or office bearers of the company responsible for day-to-day operations. The Court, while interpreting Section 34 of the Act, held that the company is the principal offender and can be prosecuted independently of its directors or responsible persons. In such cases, since

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[51] *G.L. Gupta v. D.H. Mehta (1971) 3 SCC 189; State of Karnataka v. Pratap Chand, (1981) 2 SCC 335; Sushil Goel v State, Criminal Petition No. 6875 of 2020 Order dated May 10, 2022 (Karnataka High Court)*

[52] *State of Haryana v Brij Lal Mittal, (1998) 5 SCC 343; Pepsico India Holdings Private Limited v Food Inspector, 2011 (1) SCC 176; Swapnil v. State of Maharashtra, 2024 SCC OnLine Bom 2074; Ramprakash Gulati v. State of Maharashtra, 2018 All MR (Cri) 1177; Anandkumar Satyanarayan Loya v State of Maharashtra, 2017(5) Mh.L.J. (Cri) 289*

[53] *M. K. Hameid v State through K. T. Raghu Kumar, Drug Inspector, 2023 SCC OnLine Del 5520*

[54] *Cadila Pharmaceuticals Limited v Drug Inspector, High Court of Jammu & Kashmi and Ladakh, Cr MC No. 110 of 2014 Order dated September 22, 2022 (Jammu & Kashmir and Ladakh High Court)*

imprisonment cannot be imposed upon a juristic person, the company may be punished with fine only. However, individuals responsible for the company's business cannot be prosecuted without also prosecuting the company.

- ***Insight:*** A notable distinction exists between sub-sections (1) and (2) of Section 34 of the Act. While sub-section (1) creates a presumption of guilt against persons both *in charge of* and *responsible to* the company at the time of commission of the offence, sub-section (2) creates liability for other officers (such as directors, managers, or secretaries) based on consent, connivance, or neglect.
- The Supreme Court[55] held that a person once deemed guilty under Section 34(1) cannot be punished again for the same offence under Section 34(2) of the Act. Section 34(2) applies only to those not directly responsible for the conduct of the company but who were complicit by consent, connivance, or neglect.

Quashing of criminal proceedings under the Act: Judicial trends and legal principles

The Act provides a comprehensive regulatory framework governing the manufacture, sale, and distribution of drugs and cosmetics, and entrusts the authorities including the Central Government and designated Inspectors with well-defined powers and responsibilities. Where proceedings are initiated without adherence to statutory requirements, or in the absence of a valid Central Government notification regulating, prohibiting or restricting the manufacture, sale, or distribution of a drug or cosmetic under Section 26A of the Act in such circumstances, the Courts have consistently exercised their inherent jurisdiction under Section 482 of the Code of Criminal Procedure, 1973 (now Section 528 of the Bharatiya Nagarik Suraksha Sanhita, 2023) to prevent abuse of process and to secure the ends of justice by quashing such complaints.

Grounds for Quashing Criminal Proceedings under the Act

1. Unauthorized Ban by State Authorities
2. Doctor Stocking Schedule K Drugs
3. Police Not Authorized to Initiate Proceedings
4. Non-Speaking Summoning Orders
5. Failure to Provide Sample and Analyst Report
6. Jurisdictional Error by Magistrate
7. Former Director Not Liable Post-Resignation
8. Ultra Vires Executive Directions
9. Delay Beyond Limitation Period
10. Retrospective Application of Standards

[55] *Rajasthan Pharmaceutical Laboratory v. State of Karnataka, (1981) 1 SCC 645*

- ***Insight:*** Following are some grounds on which Courts have quashed criminal proceedings initiated under the Act on account of lapses in compliance with the procedures and processes under the Act/Rules/Regulations:

  i. The Supreme Court[56] quashed an order passed by the District Magistrate, Agra, constituting a joint team to curb the sale of "alcohol mixed tinctures" and the order passed by the Drug Inspector directing a ban on the sale of aromatic tincture of cardamon. It held that (a) the authorities cannot impose their own ban or treat the drug as prohibited due to concerns over potential abuse unless and until the Central Government issues a notification under Section 26A of the Act and (b) if evidence and expert advice indicates that misuse of a lawful medicinal product is severe enough to threaten public health, then the authorities must move the Central Government to consider action under Section 26A of the Act, rather than acting unilaterally at the State level. The Court reiterated that the Act provides mechanisms for monitoring and enforcement to address substance abuse, ensuring that any prohibition conforms to the statutory process and involves centralised, scientifically guided decision-making rather than ad hoc local intervention.

  ii. The Supreme Court[57] recently quashed criminal proceedings initiated against a doctor by holding that stocking small quantities of medicine by a registered doctor for patient use, which falls under Schedule K of the Drugs and Cosmetics Rules, 1945, does not constitute an offence under Section 18(c) of the Act (which prohibits the manufacture, sale, etc., of drugs or cosmetics without a valid licence from the Licencing Authority) (forming part of Chapter IV), in view of the protection granted under Rule 123 of the Drugs and Cosmetics Rules, 1945. Rule 123 of the Drugs and Cosmetic Rules, 1945, exempts the drugs specified in Schedule K of the Rules such as quinine, antimalarial drugs, quinine sulphate, magnesium sulphate, aspirin tablets, paracetamol tablets, ointments for burn, absorbent cotton, substances used both as articles of food and drugs, such as condensed or powdered milk, farex, oats, chicken essence, Bovril, etc., from the provisions of Chapter IV of the Act.

  iii. Recently, the Supreme Court[58] reiterated that a police officer is not empowered to register an FIR and proceed in a case under the Act since such proceedings can be initiated only by a person empowered to do so under Section 32 of the Act (which prescribes the persons who can initiate proceedings for contravention of provisions of Chapter IV of the Act). It held that the police officer submitting the police report cannot be considered as an Inspector for the purpose of Section 32(1)(a) of the Act for the purpose of initiation of prosecution.

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[56] *M/s Bhagwati Medical Hall & Anr. v. Central Drugs Standard Control Organization, SLP (C) Nos. 22833-22834 of 2022 Order dated December 19, 2024 (Supreme Court)*
[57] *S. Athilakshmi v. The State represented by the Drugs Inspector, (2023) 15 SCC 651*
[58] *Rakesh Kumar v State of Bihar, SLP (criminal) No. 10373 of 2018, Order dated March 19. 2024 (Supreme Court)*

iv. The Supreme Court[59] recently quashed a non-speaking summoning order passed by the Magistrate and all the proceedings arising therefrom. It reiterated that Magistrates must briefly record the reasons reflecting application of mind when issuing process to the accused persons.

v. The Delhi High Court[60] quashed the proceedings initiated against Cipla Limited in view of the non-adherence to Section 23(4)(iii) and Section 25(2), which requires the Inspector to provide the person disclosed as manufacturer under Section 18A of the Act with a portion of the sample collected and a copy of the Government Analyst's report, respectively. In this case, a sample under Section 23(4)(iii) was not provided to Cipla Limited and was instead provided to the distributor despite Cipla Limited being disclosed as manufacturer in Form-17 filled by the Inspector.

vi. The Karnataka High Court[61] set aside the order of conviction and sentencing passed by the Magistrate for an offence under Section 27(b)(ii) of the Act (which prescribes imprisonment for a term of three to five years and a fine of minimum INR 1,00,000 or three times the value of the drugs manufactured, sold, etc., without a valid licence), holding that the Magistrate did not have the jurisdiction to try a proceeding arising out of a complaint filed by a competent officer under Section 32(1) of the Act. The Court held that the Magistrate was required to commit the matter to the Court of Sessions for trial.

vii. The Supreme Court[62] quashed proceedings initiated against a former director of a pharmaceutical company holding that he could not be held liable under Sections 18 (which prohibits the manufacture, sale, etc., of misbranded, adulterated, or spurious drugs) and 27 (which prescribes penalties for committing acts in violation of provisions of Chapter IV of the Act) of the Act for acts committed by the company after his resignation. In this case, the said Director had resigned and filed Form 32 (indicating change in status of Directors of a Company upon resignation of a Director) with the Registrar of Companies, ceasing to be associated with the company over a year before the seizure of the offending drugs during a raid. The Court held that mere mention of the former director's name on the manufacturing licence was insufficient to infer continued responsibility, especially in the absence of contrary material from the prosecution.

viii. The Himachal Pradesh High Court[63] held that State authorities cannot impose additional substantive requirements on pharmaceutical manufacturers or licensees except as provided in the Act and rules. Any such executive directions without statutory authority are unenforceable. Accordingly, the High Court quashed and set

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[59] *JM Laboratories v State of Andhra Pradesh, 2025 SCC OnLine SC 208*
[60] *M. K. Hameid v State through K. T. Raghu Kumar, Drug Inspector, 2023 SCC OnLine Del 5520*
[61] *Padma Pharmaceuticals v the State through Drug Inspector, Cr. Revision Petition No. 200077 of 2018, Order dated February 20, 2025 (Karnataka High Court)*
[62] *Yashpal Chail v. State of Uttar Pradesh & Anr., 2025 SCC OnLine SC 388*
[63] *Biogenetic Drugs Pvt. Ltd. & Anr. v. State of Himachal Pradesh & Ors., 2025 SCC OnLine HP 2522*

aside a Standard Operating Procedure issued by the State Drug Controller, which had imposed additional requirements on manufacturers of psychotropic substances, such as mandatory reporting of sales to law enforcement authorities, holding it to be *ultra vires* and issued without any authority under the Act.

ix. The Karnataka High Court[64] quashed proceedings initiated for offences under Section 27(d), (manufacturing drugs that are not of a standard quality, which is punishable with a maximum term of imprisonment of two years and minimum fine of INR 20,000) in view of the complaint having been filed after the period of limitation, i.e., nearly five years and seven months after the drug sample had been declared substandard by the Government Analyst. The delay in filing the complaint was held to be sufficient for the Court to invoke Section 468 of the Code of Criminal Procedure, 1973, which bars the Court from taking cognizance of offence after the lapse of the period of limitation specified therein.

x. The Bombay High Court,[65] while recently noting that Section 18(a)(i) of the Act prohibits manufacturing drugs not of standard quality "from such date as may be fixed by the State Government by notification in the Official Gazette", held that the notification prescribing the standard of the drugs cannot be implemented retrospectively. Liability for not meeting the standard cannot be imposed for drugs manufactured before the notification came into force. In this case, the Court found that the drug in question was manufactured in 2004 and at that time, no standard had been prescribed by the Food and Drug Administration, Maharashtra. The applicable notification prescribing such a standard for the drug was issued only in 2005, i.e., after the date of manufacture of the drug.

Applicability of the Act and Rules framed thereunder to medical trials in India

The New Drugs and Clinical Trials Rules, 2019, govern the provisions regulating the new drugs, investigational new drugs for human use, clinical trial, bioequivalence studies, bioavailability studies, and ethics committee. The clinical trials were earlier conducted in accordance with Schedule Y of the Drugs and Cosmetics Rules, 1945, and the rules governing the import and manufacture of new drugs for clinical trial were provided in Part XA of the Rules thereof. The New Drugs and Clinical Trials Rules, 2019, have superseded the Part XA and Schedule Y of the Drugs and Cosmetics Rules, 1945. Under Rule 3, the Drugs Controller, India appointed by the Central Government in the Ministry of Health and Family Welfare has been appointed as the central licensing authority. The clinical trial of a new drug or investigational new drug shall be conducted only after obtaining permission from the Central Licensing Authority and the protocol for the clinical trial having been

[64] *M/s Emcure Pharmaceuticals Ltd. & Ors. v. State of Karnataka, Karnataka High Court, Criminal Petition No. 6919 of 2022 Order dated September 22, 2022 (Karnataka High Court)*
[65] *Kirti Kumar Jayantilal Patel v. State of Maharashtra, Writ Petition 912 of 2022, Order dated March 31, 2023 (Bombay High Court)*

approved by the ethics committee *(Rule 19).* The order of the Central Licensing Authority denying the permission for conducting clinical trial can be challenged before the Central Government in the Ministry of Health and Family Welfare within 45 days from the receipt of the order *(Rule 22).*

Chapter IX of the New Drugs and Clinical Trials Rules, 2019, regulates the import of new drugs and investigational drugs for clinical trial. Rule 67 prohibits import of new drugs and investigational drugs except with in accordance with the licence granted by the Central Licencing Authority. In the event the person to whom the licence has been granted fails to comply with the provisions of the Act and the rules, the Central Licensing Authority may suspend or cancel the licence after affording the licensee an opportunity to be heard *(Rule 72).* The appeal against the order of the Central Licensing Authority shall lie before the Central Government within the period of 45 days from the receipt of the order.

Applicability of the Act and Rules to Medical Trials in India

1. Governed by New Drugs and Clinical Trials Rules, 2019.
2. Supersedes Schedule Y and Part XA of 1945 Rules.
3. Rule 19 allows trials after approval from Central Licensing Authority and Ethics Committee.
4. Rule 22 allows appeals within 45 days of denial of permission to conduct trial.
5. Rule 67 prohibits import of new drugs and investigational drugs for trial without a valid licence.
6. Licence can be suspended/cancelled for non-compliance.

- ***Insight***: In a case before the Delhi High Court,[66] the manufacturer filed a petition seeking an order directing the Ministry of Health and Family Welfare to consider the purchase and distribution of the tubal rings, manufactured by it, to the public. It was the manufacturer's case that it had established an industrial unit on the basis of a specific representation made by the Ministry of Health and Family Welfare that it will give preference for purchase to indigenous tubal rings. The Central Government opposed the petition contending that tubal ring is a "New Drug" within the meaning of Rule 122E of the Drugs and Cosmetics Rules, 1945 (which defines a "new drug", including drugs not significantly used in the Indian subcontinent), requiring clinical trial. Since the clinical trial was not conducted, the Ministry of Health and Family Welfare was not obligated to purchase the tubal ring from the manufacturer. Rejecting this contention, the Court held that tubal rings were used extensively in the country. The mere fact that it is now manufactured in the country instead of being imported does not change the character and make it a new drug within the meaning of the aforesaid rules. Since the tubal rings do not fall within the ambit of "new drugs", it does not require any clinical trial.

[66] *Corporate Channels India (P) Limited v. Union of India, 1996 SCC OnLine Del 291*

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