B2

BIOTECHNOLOGY SECTOR

DCGI/CDSCO Enforcement:

Licence Cancellation,
Banned Drug Proceedings,
Clinical Trial Violations &
Writ Defence

DCGI/CDSCO Enforcement & Drug Regulatory Litigation

Licence Suspension, Banned Drug Proceedings, NDA Challenges, Clinical Trial Violations & GMP Defence — The Complete Practitioner's Guide

Booklet II of VI — Indian Biotechnology & Life Sciences Legal Series

Advocates & Legal Consultants — Ultra-Premium Client Advisory Series

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CHAPTER ONE

DCGI/CDSCO Show-Cause Notices: Drug Licence Suspension, Cancellation Grounds and Response Strategy

Drugs and Cosmetics Act 1940, Schedule M Compliance, State Licensing Authority Powers, Central Licence Suspension Procedure and High Court Challenge Framework

> *A DCGI show-cause notice — or a State Licensing Authority suspension order — directed at a pharmaceutical manufacturer's manufacturing licence is the regulatory event that transforms a compliance discussion into a legal crisis. The immediate commercial consequences are severe:*

suspended manufacturing licences halt production at the affected facility; product recalls may be directed; export shipments are stopped at customs; WHO pre-qualification status is at risk; and regulated market customers (FDA-approved US or EMA-approved European buyers) who learn of the regulatory action may immediately terminate supply agreements. For the large Gujarat pharmaceutical company — which may operate multiple CDSCO-licensed manufacturing sites and derive substantial revenue from regulated market exports — a licence suspension's commercial impact in the first 72 hours can exceed its entire legal department's annual budget. The regulatory response must be as immediate as the commercial crisis: counsel engaged within hours, not days, of a licence suspension or show-cause notice.

1.1 The Dual Licensing Structure: State Drug Controller and CDSCO

India's pharmaceutical manufacturing licensing structure is divided between State Licensing Authorities (SLAs) — the State Drug Controllers operating under the respective State Government's Health Department — and the Central Drugs Standard Control Organisation (CDSCO) at the national level. SLAs issue manufacturing licences (Form 25 and Form 28 under the Drugs and Cosmetics Rules, 1945) for most pharmaceutical products manufactured for domestic sale; CDSCO issues manufacturing licences for new drugs, biologicals, vaccines, and products subject to central licensing under Schedule C and C1. This dual structure means that a CDSCO action (typically targeting new drugs, biologicals, or products of national concern) and an SLA action (targeting the manufacturing facility's GMP compliance for domestic-market products) are separate regulatory proceedings with different authorities, different procedural rules, and potentially different timelines — and a large manufacturing company facing both simultaneously must manage two parallel regulatory engagement tracks. The Gujarat Food and Drug Control Administration (FDCA) — the SLA for Gujarat — is the immediate regulatory authority for Gujarat-based manufacturers, and its inspection regime, show-cause procedures, and enforcement escalation protocols are the first layer of regulatory risk management that Gujarat-based pharma companies must navigate.

1.2 Show-Cause Procedure: Natural Justice Requirements and Response Timing

The Drugs and Cosmetics Act does not prescribe a detailed show-cause procedure for licence suspension or cancellation — the procedural requirements derive from the principles of natural justice applicable to all quasi-judicial actions affecting rights. The SLA or CDSCO must: issue a show-cause notice specifying the precise grounds for the proposed action (the inspection observations, the test failures, or the compliance violations alleged); allow the manufacturer a reasonable time to respond (in practice, 15-30 days, though urgent situations may have shorter timelines); consider the manufacturer's response on its merits; and give the manufacturer an opportunity for a personal hearing before any adverse order is passed. A licence suspension or cancellation order issued without a show-cause notice — or without considering the manufacturer's response — is procedurally defective and vulnerable to challenge in a High Court

writ petition on natural justice grounds. The Gujarat FDCA's show-cause procedures have been the subject of several High Court of Gujarat decisions that have clarified the minimum procedural requirements: the show-cause notice must identify specific products and specific facilities affected; the grounds must be stated with sufficient particularity to enable a meaningful response; and the hearing opportunity must be genuine, not merely formal. For the manufacturer's legal counsel, the show-cause response is the most critical document in the enforcement proceeding: it must address every ground specifically, provide documentary evidence refuting each allegation, demonstrate corrective actions already taken, and present an expert assessment (GMP consultant's report) validating the adequacy of the remediation. A superficial show-cause response that acknowledges deficiencies without demonstrating remediation typically results in a licence suspension; a detailed, evidence-supported response that demonstrates good-faith corrective action creates the possibility of a voluntary undertaking-based resolution without formal suspension.

> **KEY PROVISION**
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> Section 18A, Drugs and Cosmetics Act 1940: "No person shall manufacture for sale or for distribution, or stock or exhibit or offer for sale, or distribute— (i) any drug other than under and in accordance with conditions of a licence issued for such purpose under this Chapter; (ii) any cosmetic other than under and in accordance with conditions of a licence issued for such purpose under this Chapter."

1.3 Schedule M Compliance: The GMP Standard and Its Interpretation

Schedule M of the Drugs and Cosmetics Rules — which sets out the Good Manufacturing Practices for premises, plant and equipment in the Indian pharmaceutical industry, most recently revised in 2023 to align with WHO GMP standards — is the primary technical standard against which CDSCO and State Drug Controllers assess a pharmaceutical manufacturer's facilities. The revised Schedule M (notified in December 2023, with implementation timelines for different size categories) introduces requirements that significantly raise the compliance bar for smaller and medium manufacturers: quality management systems aligned with ICH Q10; enhanced change control and deviation management requirements; validated cleaning procedures documented by analytical testing; stability testing protocols aligned with ICH Q1 guidelines; and qualification and validation documentation for all critical manufacturing equipment. For large Gujarat pharmaceutical companies — which typically already operate to WHO GMP or FDA-level standards — the revised Schedule M compliance burden is a matter of documentation and audit-readiness rather than fundamental facility upgrade. However, the revised Schedule M creates a significant enforcement risk for mid-size manufacturers that have not yet implemented the full documentation and validation requirements: a CDSCO inspection conducted against the revised Schedule M standard will generate non-compliance observations even at facilities that are operationally sound, if the documentation does not meet the enhanced standard. Practitioners advising pharmaceutical manufacturers on regulatory compliance must

assess, for each client, whether the revised Schedule M implementation is complete and documentable — because a non-compliant facility is a licence enforcement risk regardless of the product's actual quality.

1.4 High Court Writ Challenge to Licence Suspension: Grounds and Interim Relief Strategy

A pharmaceutical manufacturer whose licence has been suspended — or whose show-cause response has been rejected and a suspension order issued — has two primary avenues for immediate legal relief: an appeal to the Central Government (the prescribed appellate authority under the Drugs and Cosmetics Act), and a writ petition to the High Court under Article 226 of the Constitution challenging the suspension order. The High Court writ is frequently the faster and more commercially effective route: the Central Government appellate process is slow (often taking months) and does not guarantee a stay of the suspension during the appeal; the High Court can grant an interim stay of the suspension order within 24-48 hours of the petition's filing, allowing production to resume while the challenge is adjudicated. The grounds for writ challenge of a licence suspension include: procedural defects in the show-cause process (inadequate notice, failure to hold a genuine hearing, failure to consider evidence submitted by the manufacturer); factual errors in the suspension order (findings of non-compliance that are incorrect on the documented evidence); disproportionality (a suspension of the entire facility for non-compliance in one product area or one manufacturing block, where the appropriate response would be a targeted action rather than a facility-wide suspension); and legal errors in the application of the Schedule M standard. The interim stay application must be supported by an affidavit from a GMP expert (ideally a consultant with regulatory agency experience) attesting to the current compliance status of the facility and the corrective actions taken since the inspection — the High Court's grant of an interim stay is typically conditioned on the manufacturer demonstrating that it has addressed the deficiencies identified in the inspection, even if the validity of the underlying suspension order is disputed.

CHAPTER TWO

Banned Drug Proceedings: Section 26A Orders, Judicial Review and the Public Interest Defence

Drugs and Cosmetics Act Section 26A, Central Government Banning Powers, Expert Committee Review Process, Fixed-Dose Combination Bans and Judicial Review Standard

> *The Central Government's power under Section 26A of the Drugs and Cosmetics Act to prohibit the manufacture, sale, or distribution of any drug in the public interest — without the procedural safeguards applicable to individual licence actions — is the most commercially disruptive regulatory power in the pharmaceutical sector's regulatory framework. A Section 26A ban order, if upheld, eliminates overnight the entire commercial value of the manufacturer's investment in the affected product — the manufacturing licence, the marketing approvals, the registered trademarks, and the market position built over years of commercial activity. The 2016 Fixed-Dose Combination (FDC) bans — which prohibited 344 FDC drug products under Section 26A — resulted in some of the most commercially significant pharmaceutical regulatory litigation in Indian legal history, ultimately addressed by the Supreme Court in Union of India v. Pfizer Ltd. (2017) 2 SCC 1.*

2.1 The Section 26A Power: Scope and the Expert Committee Requirement

Section 26A empowers the Central Government to prohibit the manufacture, sale, or distribution of any drug or cosmetic if it is satisfied, after consultation with the Drugs Technical Advisory Board (DTAB), that the use of the drug or cosmetic is likely to involve any risk to human beings or animals, or that the drug does not have the therapeutic value claimed. The Supreme Court in Pfizer held that the Central Government's satisfaction under Section 26A must be based on adequate and relevant materials — the expert committee's opinion, which must itself be based on an examination of scientific evidence — and that a Section 26A ban order issued without adequate consultation with the DTAB, or based on an expert committee opinion that did not examine the manufacturer's submissions, is procedurally flawed. This ruling established that manufacturers whose products are proposed to be banned have a right to be heard before the expert committee — the opportunity to submit scientific evidence supporting the product's safety and efficacy — and that a ban order that does not engage with the manufacturer's submissions is vulnerable to judicial review on natural justice grounds. For manufacturers of FDC products currently under Section 26A scrutiny — and the DCGI's ongoing programme of FDC review continues to identify additional combination products for potential banning — the active engagement with the expert committee process (submission of clinical data supporting the FDC's therapeutic rationale and safety profile) is the primary regulatory advocacy strategy that must precede any litigation response.

LEADING CASE

Union of India v. Pfizer Ltd. & Ors. (2017) 2 SCC 1: The Supreme Court upheld the Central Government's power to ban FDCs under Section 26A but remanded the specific ban orders for re-examination by fresh expert committees, on the ground that the expert committees that reviewed the FDCs had not been given — and had not examined — the scientific data that manufacturers had sought to place before them. The Court held that the manufacturers' right to a hearing before the expert committee was an element of the procedural fairness required for a valid Section 26A order. This ruling has shaped the post-2017 FDC ban process, with the DTAB/expert committee proceedings now including a formal manufacturer submission and presentation stage before any ban recommendation is made.

2.2 Post-Pfizer FDC Litigation: Strategic Lessons and Current Battleground

The Supreme Court's remand in Pfizer — which directed fresh expert committee review of the banned FDCs, with opportunity for manufacturers to present data — resulted in several rounds of expert committee proceedings, some of which confirmed the ban (where the expert committee found no adequate clinical evidence supporting the FDC's combination rationale) and some of which reversed the ban (where manufacturers successfully demonstrated clinical evidence for the combination). The ongoing FDC review process has created a recurring litigation risk for manufacturers of combination products across therapeutic categories — antimicrobial combinations, pain management combinations, cold and cough combinations, and nutritional supplement combinations all remain subject to the possibility of Section 26A scrutiny if post-marketing safety signals or prescribing pattern data suggest public health concerns. For large pharmaceutical companies with significant FDC portfolios — a common product category for Gujarat's large generics, which have built market positions in the domestic OTC and prescription markets with combination products — the proactive compliance strategy is to maintain a clinical evidence dossier for every significant FDC product, updated with current prescribing guidelines and post-marketing safety data, so that if a Section 26A proceeding is initiated, the manufacturer can present a credible and contemporaneous scientific case in the expert committee without needing to commission emergency studies after the regulatory action has begun.

CHAPTER THREE

New Drug Approval Disputes: NDA Rejection Challenges, CDSCO Expert Committee Review and Writ Jurisdiction

New Drugs and Clinical Trials Rules 2019, NDA Application Process, Expert Committee Technical Objections, CDSCO Rejection Orders and High Court Review of Regulatory Approval Decisions

3.1 The New Drug Approval Process Under the NDCT Rules 2019

The New Drugs and Clinical Trials (NDCT) Rules, 2019 — which replaced the previous clinical trials regulatory framework under Schedule Y of the Drugs and Cosmetics Rules — establish the comprehensive regulatory pathway for the approval of new drugs and new biological entities in India. The NDCT Rules distinguish between: New Drug Applications (NDAs) for new chemical entities with full clinical data; applications for already-approved drugs seeking approval in India on the basis of data from other jurisdictions (with waiver of local clinical trial requirements for certain categories); and applications for new biological entities and biosimilars. The CDSCO's review of NDA applications involves: a technical review by subject experts within CDSCO; referral to subject expert committees (SECs) for complex or novel applications; and a final decision by the DCGI after considering the SEC's recommendation. The SEC recommendation is the critical decision point — a SEC that recommends rejection, or that recommends conditional approval with requirements that the applicant considers unreasonable, determines the regulatory trajectory. Manufacturers whose NDA applications have been rejected by the CDSCO — or whose products have been approved with conditions that make the approval commercially unviable — have the right to seek review within the CDSCO process and, where administrative remedies are exhausted, to challenge the rejection decision through a writ petition in the High Court.

3.2 Judicial Review of CDSCO Decisions: The Standard of Review and Its Limits

The High Court's power of judicial review over CDSCO drug approval decisions — and specifically over NDA rejections — is a supervisory jurisdiction, not an appellate jurisdiction: the Court does not substitute its scientific judgment for the CDSCO's, but reviews whether the CDSCO's decision was made according to law, based on relevant considerations, free from procedural impropriety, and proportionate to the regulatory objective. The standard of review applicable to expert regulatory decisions in India — as established by the Supreme Court in a series of cases on judicial review of regulatory and administrative decisions — is the "Wednesbury unreasonableness" standard: the Court will interfere only if the decision is so unreasonable that no reasonable regulatory authority could have reached it. In pharmaceutical

NDA rejection cases, the grounds on which courts have interfered include: rejection based on a criterion not prescribed in the NDCT Rules or applicable guidelines; rejection without giving the applicant an opportunity to address specific objections that were raised for the first time in the rejection order; and rejection based on a factual finding that is contradicted by the applicant's documented submissions. The practitioner drafting a writ petition challenging an NDA rejection must identify the specific legal error — the procedural defect, the irrelevant consideration relied on, or the prescribed criterion misapplied — rather than inviting the Court to re-evaluate the scientific merits of the application.

CHAPTER FOUR

Clinical Trial Violations: CDSCO Enforcement, Ethics Committee Disputes and Stop-Trial Orders

NDCT Rules 2019 Compliance Obligations, Sponsor Responsibilities, Ethics Committee Registration and Oversight, Serious Adverse Event Reporting and CDSCO Enforcement Powers

4.1 Sponsor Responsibilities Under the NDCT Rules 2019

A clinical trial sponsor — whether a pharmaceutical company sponsoring a study for its own product's NDA, a Contract Research Organisation acting as sponsor, or an academic institution conducting investigator-initiated research — bears primary regulatory responsibility for the conduct of the trial under the NDCT Rules 2019. The sponsor's obligations include: registration of the clinical trial with the Clinical Trials Registry of India (CTRI) before enrolment begins; obtaining CDSCO permission for each phase of clinical trials involving new drugs; ensuring that the trial is conducted in accordance with the approved protocol, ICH E6 Good Clinical Practice (GCP) guidelines, and the Declaration of Helsinki; appointing an independent Data Safety Monitoring Board (DSMB) for Phase III trials; reporting Serious Adverse Events (SAEs) to the CDSCO within specified timelines (fatal and life-threatening SAEs within 24 hours; other SAEs within 7 days); maintaining trial master files; and ensuring the provision of free medical management and compensation to trial subjects who experience trial-related injury. CDSCO's enforcement actions against clinical trial sponsors — which have increased significantly since the 2013 reforms following the parliamentary committee's critique of the clinical trial regulatory framework — include: warning letters for protocol deviations; suspension of ongoing trials pending investigation; cancellation of CDSCO permission for the specific trial; and prohibition on the sponsor from conducting further clinical trials in India. For pharmaceutical companies with active clinical development programmes in India — including foreign pharma companies that use India's large patient population and lower trial costs for global development programmes — the compliance infrastructure to meet these obligations is a significant operational investment, and its adequacy is the primary determinant of CDSCO enforcement risk.

4.2 Compensation for Clinical Trial Subject Injury: The Quantum Formula Dispute

The CDSCO's 2013 and 2019 guidelines on compensation for trial-related injury — which established a formula for computing compensation payable to clinical trial subjects who experience study-related injury or death — have generated persistent disputes between sponsors, ethics committees, and regulators on the application of the formula to specific cases. The compensation formula (based on the subject's age, income, and the degree of the injury's relationship to the trial) was designed to provide prompt, formula-based compensation without

requiring the subject or the subject's family to litigate causation — the formula applies even where causation is not conclusively established, if the injury occurred while the subject was enrolled and the DSMB or the sponsor's medical monitor cannot rule out a trial-related cause. For large pharmaceutical sponsors, the compensation formula's "probable" causation standard — lower than the "balance of probabilities" standard applicable in civil liability — creates a financial exposure that is difficult to precisely quantify when planning a large Phase III trial with several hundred subjects. Practitioners advising trial sponsors on the compensation framework must build the compensation obligation into the trial's financial modelling; ensure that the trial's indemnity insurance covers formula-based compensation payments; and draft the informed consent document in a manner that accurately reflects the compensation mechanism (without representing it as full and final compensation for all trial-related harm, since the formula is a minimum and does not bar subsequent civil claims for additional damages).

CHAPTER FIVE

Good Manufacturing Practice Failures: CDSCO Inspection, WHO Pre-Qualification Loss and Export Licence Consequences

Schedule M Compliance, CDSCO Import Alert Consequences, WHO Pre-Qualification Programme, US FDA 483 Observations and Export Restriction Proceedings

5.1 The Cascading Impact of GMP Failure: Domestic and Export Consequences

A GMP failure at a Gujarat pharmaceutical manufacturer's facility — whether identified in a CDSCO inspection, a WHO pre-qualification assessment, a US FDA inspection, or a European EMA GMP inspection — triggers a cascade of regulatory consequences that affect both the domestic manufacturing licence and the facility's eligibility to export to regulated markets. The sequence of consequences is: the domestic SLA/CDSCO action (licence suspension, mandatory recall, stop-manufacture order); the WHO pre-qualification office's response (suspension of pre-qualified product status, which affects the facility's eligibility to supply to UN agencies and government procurement programmes that specify WHO pre-qualified suppliers); and the regulated market agency's response (import alert from the US FDA barring importation of products from the flagged facility, or EMA GMP non-compliance opinion that results in EU member states' withdrawal of import licences for products from the facility). The commercial impact of a US FDA import alert — which bars all pharmaceutical products from a listed facility from entering the US market until the import alert is resolved — is particularly severe for Gujarat's large generics that derive 30-50 per cent of their revenues from the US market. Import alert resolution requires: a facility remediation programme; a CAPA (Corrective Action and Preventive Action) plan submitted to the FDA; a re-inspection by FDA or a third-party consultant's audit accepted by the FDA; and in some cases, a consent decree with the FDA that specifies ongoing compliance obligations and penalty provisions for future failures. Practitioners advising pharmaceutical companies on import alert response must coordinate the legal strategy with the technical remediation: the CAPA plan is simultaneously a regulatory document (submitted to the FDA as evidence of remediation) and a legal document (creating commitments that, if not fulfilled, generate additional enforcement exposure).

CHAPTER SIX

Spurious and Adulterated Drugs: Criminal Prosecution Under the Drugs and Cosmetics Act, Bail and Defence Strategy

Drugs and Cosmetics Act Sections 17A, 27, 28, Criminal Prosecution Framework, Cognisable and Non-Cognisable Offences, Bail Applications and Defence at Trial

6.1 Criminal Liability Under the Drugs and Cosmetics Act: The Offence Framework

The Drugs and Cosmetics Act creates a comprehensive criminal liability framework for the manufacture, sale, and distribution of substandard, spurious, and adulterated drugs — with penalties that range from fines for minor violations to imprisonment for life for the manufacture of spurious drugs that cause death. The Act defines a hierarchy of offences: "Not of Standard Quality" (NSQ) drugs — those that fail pharmacopoeial specifications but are not fraudulently misrepresented — attract lesser penalties than spurious drugs (those that are manufactured and sold under a name belonging to another manufacturer) and adulterated drugs (those that contain ingredients other than those stated in the label). The criminal prosecution of pharmaceutical manufacturers and their responsible personnel (typically the manufacturer, the manufacturing chemist, and the qualified person named on the licence) under Section 27 of the Act — which attracts imprisonment up to 3 years for NSQ and up to 10 years or life imprisonment for spurious/adulterated drugs that cause injury or death — is a regularly used enforcement tool by State Drug Controllers, and Gujarat FDCA has historically been an active prosecutor in drug quality enforcement matters. For a pharmaceutical manufacturer or its responsible personnel facing criminal prosecution under the Act, the immediate priorities are: bail (anticipatory bail under Section 438 CrPC if the offence is non-bailable and arrest is apprehended; regular bail after arrest); quashing of the complaint in appropriate cases under Section 482 CrPC if the complaint is legally infirm; and preparation of the technical defence (expert evidence on analytical methods, reference standards, and the adequacy of the prosecution's sampling and testing procedures).

6.2 Anticipatory Bail in Drug Prosecution: Strategy and Judicial Approach

The Gujarat High Court's approach to anticipatory bail in drug prosecution matters — particularly for offences under Sections 27 and 28 of the Drugs and Cosmetics Act — reflects the tension between the seriousness of drug quality offences (which affect public health) and the principle that accused persons should not be subjected to pre-trial detention unless flight risk or evidence tampering risk is established. For responsible persons named in drug prosecution complaints — manufacturing chemists, quality control heads, and directors whose names appear

on the manufacturing licence — anticipatory bail is typically available provided: the applicant is not a flight risk; the applicant cooperates with the investigation; and the alleged offence does not involve death or serious injury to consumers. The High Court of Gujarat has, in several anticipatory bail applications, focused on the technical reliability of the prosecution's test results: where the manufacturer can demonstrate that the prosecution's testing was conducted at a non-accredited laboratory, that the reference standard used was past its expiry date, that the sampling procedure was not followed in accordance with the Drugs and Cosmetics Rules, or that a retest at an independent laboratory produces a conforming result, these technical vulnerabilities in the prosecution case are relevant to the bail application and can support a finding that the prosecution's case does not meet the threshold of a prima facie case for a non-bailable offence.

Booklet II Complete Summary: DCGI/CDSCO regulatory enforcement — from licence suspension through Section 26A banning orders, NDA rejection challenges, and GMP enforcement — is the core regulatory risk management practice for India's large pharmaceutical and biotech sector. Gujarat's pharmaceutical cluster faces a dual enforcement challenge: the FDCA's domestic manufacturing licence enforcement and the CDSCO's central product safety enforcement, simultaneously with the US FDA, EMA, and WHO's export market regulatory oversight. The criminal prosecution framework under the Drugs and Cosmetics Act — with its life imprisonment provisions for spurious drugs — demands that large manufacturers maintain the technical quality systems and documentation infrastructure that make criminal liability theoretically impossible and practically defensible. Counsel who understands the Schedule M standard, the Section 26A procedure, the NDCT Rules' clinical trial obligations, and the criminal sentencing framework is the practitioner who delivers genuine value in this practice area.