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BIOTECHNOLOGY SECTOR

# Drug Price Control & NPPA Proceedings:

DPCO 2013, Overpricing Liability, Recovery with Interest & High Court Challenge

BHATT & JOSHI ASSOCIATES — INDIAN BIOTECHNOLOGY & LIFE SCIENCES LEGAL SERIES

# Drug Price Control & NPPA Proceedings

*DPCO 2013, Overpricing Liability, Recovery with Interest, Ceiling Price Challenges & High Court Strategy — The Complete Practitioner's Guide*

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

Advocates & Legal Consultants — Ultra-Premium Client Advisory Series



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CHAPTER ONE

# DPCO 2013: Scheduled Drug Price Control, MAPE Ceiling, Para 19 Overpricing and NPPA Enforcement Mechanics

*Drugs (Prices Control) Order 2013, Essential Medicines List, MAPE of 16%, Ceiling Price Formula, Para 19 Overpricing Prohibition and NPPA Demand Notice Framework*

> *Drug price control enforcement — the NPPA's demand notices for overpricing under the Drugs (Prices Control) Order 2013, followed by recovery proceedings for amounts alleged to have been overcharged with interest at 15 per cent per annum — is the regulatory risk that keeps the CFOs of India's large pharmaceutical companies awake at night. A single NPPA demand notice, covering*

*a product that has been sold in large volumes for several years at a price the NPPA now claims exceeded the ceiling, can carry an overpriced amount in the hundreds of crores — and the 15 per cent annual interest on the overcharged amount, running from the date of each overpriced sale, can dwarf the principal. For a Gujarat pharmaceutical company with a large portfolio of scheduled formulations in the essential medicines list, the NPPA's price monitoring programme is a continuous enforcement risk that demands systematic pricing compliance and proactive legal review of every new product launch and every price revision decision.*

### 1.1 The DPCO 2013 Framework: Which Products Are Controlled and at What Price

The Drugs (Prices Control) Order 2013 controls the retail prices of medicines specified in the National List of Essential Medicines (NLEM) — currently comprising approximately 384 formulations covering a wide range of therapeutic categories including antibiotics, cardiovascular medicines, anti-diabetics, anti-cancer medicines, and vaccines. For these "scheduled formulations," the NPPA computes a ceiling price using the formula: Ceiling Price = (Average of all prices of a particular strength and dosage form of a medicine in which the manufacturer holds at least 1 per cent market share) + 16 per cent Maximum Allowable Post-manufacturing Expense (MAPE). The ceiling price computed by the NPPA is notified in the official gazette and becomes the maximum retail price (MRP) at which the scheduled formulation can be sold — no manufacturer can charge a retail price above the ceiling price, and any amount charged above the ceiling is "overcharged" under Para 19 of the DPCO, recoverable by the NPPA with 15 per cent annual interest. For manufacturers, the critical compliance question is: has the MRP printed on the product's label (and charged from stockists and retailers) stayed within the NPPA-notified ceiling price at all times since the ceiling price was notified? Any upward price revision by the manufacturer that takes the MRP above the ceiling — even if unintentional, even if the ceiling price notification was not brought to the manufacturer's attention promptly — is an overpricing under Para 19, and the NPPA's demand notice will cover the entire volume of overpriced sales from the date the ceiling was exceeded.

**KEY PROVISION**

Para 19, DPCO 2013: "No manufacturer, importer, distributor, dealer or retailer shall sell any scheduled formulation at a price exceeding the ceiling price or the retail price fixed under this Order. The manufacturer, importer, distributor or retailer who charges more than the price so fixed shall be liable to deposit the overcharged amount together with interest thereon at the rate of 15 percent per annum from the date of such overcharging."

### 1.2 NPPA's Enforcement Process: Market Intelligence, Computation and Demand Notice

The NPPA's enforcement process begins with market intelligence gathering — NPPA price monitoring officers survey retail chemist outlets across India, collect price lists from stockists, and analyse the manufacturer's MRP from publicly reported sources (including ORG/AIOCD

market audit data, which the NPPA accesses as part of its price monitoring programme) to identify whether any manufacturer's retail price has exceeded the notified ceiling. Where overpricing is identified, the NPPA's enforcement division computes the overcharged amount: the difference between the manufacturer's charged MRP and the ceiling price, multiplied by the volume of overpriced units sold, for the period during which the overpricing occurred. The computation methodology — specifically the volume and period of overpriced sales — is the primary target of challenge in overpricing recovery proceedings: NPPA typically uses AIOCD market audit data to estimate the volume of sales, and this data (which is based on a sample of retail chemists, not actual manufacturer invoice records) frequently overstates the volume of the specific overpriced product sold through price-controlled channels. A manufacturer challenging an NPPA demand notice must obtain its own actual sales data — invoice-level records from distributors, broken down by product, pack size, and pricing period — and present this to demonstrate that the NPPA's volume computation is inflated. A 20 per cent variance between the NPPA's estimated volume and the manufacturer's actual sales, on a Rs. 100 crore demand, represents Rs. 20 crore in dispute — more than the cost of a detailed forensic reconciliation exercise.

### 1.3 Interest at 15% Per Annum: The Quantum Calculation and Challenge Points

The DPCO's 15 per cent annual interest on the overcharged amount — running from the date of each overpriced sale — creates a compounding liability that significantly exceeds the principal overcharged amount for products that have been sold above the ceiling price for several years before the NPPA's enforcement action. A manufacturer that overcharged by Rs. 50 crore on sales over a three-year period faces an interest liability of approximately Rs. 22.5 crore at simple interest, bringing the total demand to Rs. 72.5 crore — a 45 per cent premium on the principal. In cases where the overpricing period is longer — five or more years — the interest component can approach or exceed the principal. Challenging the interest computation requires: establishing the precise start date of the overpricing (where the manufacturer's MRP was within the ceiling price before a NPPA revision reduced the ceiling below the existing MRP, the overpricing period begins only from the date of the revised ceiling's gazette notification, not from any earlier date); arguing for simple rather than compound interest (the DPCO's language says "interest at the rate of 15 percent per annum" without specifying compounding, and the manufacturer's argument that simple interest applies has been accepted by some High Courts); and contending that the NPPA must deduct the manufacturer's own pricing revision (reducing the MRP to comply with the ceiling) from the start of the recovery period.

CHAPTER TWO

# NPPA Overpricing Claims: Computation of Overcharged Amount, Interest at 15% and the Demand Notice Challenge

*Para 19 Recovery Proceedings, NPPA Demand Notice Format, Volume Computation Disputes, Challenging AIOCD Data and High Court Writ Against Recovery*

## 2.1 The NPPA Demand Notice: Legal Character and Response Timeline

An NPPA demand notice issued under Para 19 of the DPCO 2013 — directing a manufacturer to deposit the overcharged amount with interest within a specified period — is a quasi-judicial demand, not a court order, and does not in itself create an obligation to pay without further proceedings if the manufacturer disputes the amount. The manufacturer's response to an NPPA demand notice has two parallel tracks: an administrative challenge through the NPPA's internal review mechanism (submitting a detailed representation to the NPPA with the manufacturer's own computation of the overcharged amount, or challenging the applicability of the ceiling price to the specific product formulation); and a judicial challenge through a writ petition to the High Court, seeking either a stay of the recovery demand or a quashing of the demand notice on legal grounds. The High Court of Delhi — which has territorial jurisdiction over NPPA actions (NPPA being headquartered in New Delhi) — is the primary forum for writ challenges to NPPA demand notices, and the Delhi High Court's drug pricing jurisprudence is the most developed body of case law on DPCO 2013 issues. However, Gujarat-based manufacturers can also file writ petitions in the High Court of Gujarat on the ground that the cause of action (the sale of the overpriced product) arose partly in Gujarat, and the Gujarat High Court's more manageable docket may offer faster hearing dates on urgent interim relief applications.

## 2.2 Challenging the Ceiling Price Computation: Methodology and Market Share Disputes

The NPPA's ceiling price computation — based on the simple average of prices of all brands in the market that have at least 1 per cent market share — can be challenged where the NPPA has incorrectly determined the universe of competing brands, used incorrect market share data, or computed the average price using pre-revision prices rather than current prices. The 1 per cent market share threshold — which determines which brands are included in the price average that forms the basis of the ceiling — is derived from AIOCD market audit data, and this data's accuracy is contestable: a brand that has exactly 0.99 per cent market share (and is therefore excluded from the averaging computation) may in fact have over 1 per cent market share if the AIOCD sample is corrected for geographic or channel bias. Including additional brands in the

averaging computation changes the average price and therefore the ceiling price — and a ceiling price that is even marginally higher than the NPPA's notified ceiling is the difference between a Rs. 100 crore overpricing demand and no demand at all. Manufacturers with products in therapeutic categories where the NPPA's ceiling price computation methodology is disputable must commission an independent market data analysis from a pharma market research firm — cross-checking the AIOCD data against alternative data sources — before deciding whether to challenge the ceiling price itself or to focus exclusively on the overcharged volume and period.

CHAPTER THREE

# Non-Scheduled Formulations: Para 20 Price Monitoring, Ceiling Price Violations and Industry Challenge Strategy

*Para 20 DPCO 2013, 10% Annual Price Increase Ceiling, NPPA Para 20 Monitoring, Non-Scheduled Overpricing and Price Revision Procedures*

## 3.1 Para 20 Control: The 10% Annual Ceiling and Its Computational Complexity

Non-scheduled formulations — the majority of pharmaceutical products in India's market that are not included in the NLEM's scheduled formulations list — are subject to Para 20 of the DPCO 2013, which prohibits manufacturers from increasing the MRP of any non-scheduled formulation by more than 10 per cent in any twelve-month period. The Para 20 10 per cent ceiling applies to increases in the existing MRP — not to new product launches, which can be priced freely — and is computed on a product-by-product, pack-by-pack, strength-by-strength basis. The compliance complexity of Para 20 for a large pharmaceutical company with several hundred non-scheduled SKUs (stock-keeping units) in its product portfolio is substantial: each annual price revision decision must be checked against the last MRP revision date and the last revised MRP for each specific SKU, to ensure that the new MRP does not exceed the old MRP by more than 10 per cent. Computational errors — particularly in companies that manage pricing through legacy ERP systems that do not automatically apply the Para 20 ceiling to revision proposals — are the most common source of Para 20 overpricing: a company that revises 300 SKU prices annually, with 1 per cent of revisions inadvertently exceeding the 10 per cent ceiling by even a small margin, is generating 3 Para 20 violations per year that accumulate across years of product portfolio management. The NPPA's Para 20 enforcement — historically less active than Para 19 enforcement but increasing — focuses on the high-value brands in the non-scheduled segment, where even modest percentage overpricing on high-volume products generates significant absolute overcharging figures.

CHAPTER FOUR

# Revision of Ceiling Prices: Annual Revision, Extraordinary Revision Applications and Judicial Review

*Para 16 Annual WPI Revision, Para 21 Extraordinary Revision Applications, Cost-Increase Justification and Judicial Review of NPPA Revision Decisions*

## 4.1 Annual WPI Revision: The Automatic Adjustment Mechanism

Para 16 of the DPCO 2013 provides for an annual revision of ceiling prices for scheduled formulations — not through a renegotiation of the ceiling price formula, but through an automatic adjustment indexed to the Wholesale Price Index (WPI). The annual WPI adjustment allows scheduled formulation ceiling prices to increase (or decrease) in line with the annual percentage change in the WPI for the pharmaceutical sector, preserving the real value of the ceiling price over time. For manufacturers, the WPI revision mechanism is both a protection (preventing inflation from eroding margins below viability) and a limitation (the ceiling price can only increase by the WPI percentage, regardless of specific input cost increases that may exceed WPI — such as API price increases driven by supply chain disruptions, currency depreciation for imported raw materials, or regulatory compliance cost increases). The practical implication is that a manufacturer whose cost base increases faster than WPI — a situation common for specialty generics and biologics manufacturers whose key API costs are import-linked and subject to exchange rate movements — faces margin compression that cannot be addressed through the annual WPI revision mechanism alone, and must pursue an extraordinary revision under Para 21 if the cost increase is to be reflected in the ceiling price.

## 4.2 Para 21 Extraordinary Revision: The Application Procedure and NPPA's Discretion

Para 21 of the DPCO 2013 empowers the NPPA to revise the ceiling price of any scheduled formulation at any time — upward or downward — if it is satisfied that an extraordinary revision is warranted due to a significant change in the cost of the formulation. A manufacturer whose ceiling price has become non-viable due to API cost increases, formulation technology upgrades, or quality compliance cost escalation can apply to the NPPA under Para 21 for an upward revision of the ceiling price, supported by a detailed cost structure submission. The NPPA's Para 21 revision decisions are quasi-judicial decisions that are subject to challenge in the High Court where the NPPA has: rejected a Para 21 application without considering the cost evidence; applied an incorrect cost model in assessing the revision application; or taken an unreasonably long time to decide the application (leaving the manufacturer in the position of selling below cost while the NPPA's deliberations continue). The standard of judicial review applicable to

NPPA's Para 21 decisions — as with other regulatory economic decisions — is the reasonableness standard: the Court will not substitute its judgment for the NPPA's on the appropriate ceiling price, but will interfere if the NPPA's decision is arbitrary, based on irrelevant considerations, or so unreasonable that no reasonable regulator could have reached it on the evidence before it.

CHAPTER FIVE

# NPPA Litigation: Writ Petitions Against Recovery Notices, High Court Interim Relief and Constitutional Challenges

*Article 226 Writ Jurisdiction Over NPPA Decisions, Stay of Recovery, Constitutional Validity of DPCO 2013 and Right to Carry on Trade Under Article 19(1)(g)*

## 5.1 Writ Jurisdiction and the High Court's Role in DPCO Enforcement

The High Court's writ jurisdiction under Article 226 of the Constitution is the primary forum for pharmaceutical companies challenging NPPA demand notices, ceiling price notifications, and recovery proceedings. The DPCO 2013 does not provide an internal appellate mechanism for challenging NPPA demand notices — the only formal administrative remedy is a representation to the NPPA itself, which is not an independent review. This absence of an independent administrative appeal makes the High Court writ petition the first-instance judicial forum for DPCO disputes, and the High Court's jurisdiction to stay the NPPA's recovery demand pending the writ petition's disposal is the most immediately valuable relief for a manufacturer facing a large demand notice. The interim stay of an NPPA recovery demand — which prevents the NPPA from initiating recovery proceedings (including seizing the manufacturer's bank accounts or immovable property) while the writ is pending — is available where the manufacturer demonstrates: a prima facie case that the demand is legally or factually incorrect; irreparable harm from the recovery (affecting the manufacturer's working capital and production capacity); and balance of convenience favouring a stay. For large NPPA demands, the High Courts consistently require the manufacturer to deposit a percentage of the disputed amount as a condition of the interim stay — a balance between protecting the NPPA's revenue interest and not requiring full pre-deposit (which would defeat the purpose of the stay for a manufacturer challenging the demand's correctness).

CHAPTER SIX

# Pharma Price Control and the Competition Law Interface: CCI Investigations and Parallel NPPA Proceedings

*Competition Act 2002 Sections 3 and 4, CCI Pharma Sector Investigations, Parallel NPPA and CCI Proceedings, Information Exchange Risks and Cartel Exposure*

## 6.1 CCI Investigations in the Pharmaceutical Sector: Scope and Triggers

The Competition Commission of India (CCI) has, over the past decade, established a significant enforcement presence in the pharmaceutical sector — investigating: alleged anti-competitive agreements among pharmaceutical manufacturers (price-fixing, market allocation, and information exchange through industry associations); abuse of dominant position by originator companies in patented drug markets (excessive pricing, refusal to license, and bundling); and vertical restraints in the pharmaceutical distribution chain (exclusive dealing arrangements, resale price maintenance through manufacturer-imposed MRP, and tie-in arrangements between pharmaceutical manufacturers and diagnostic services). For a pharmaceutical company that is simultaneously subject to NPPA price control enforcement and a CCI investigation — a situation that arises where the CCI investigates pricing behaviour in a market that is also subject to DPCO ceiling prices — the interaction between the two proceedings creates complex legal challenges: the manufacturer's NPPA defence (that its prices were within the DPCO ceiling) is not a complete CCI defence (since the CCI may allege that the manufacturer coordinated with competitors to set prices at the ceiling level rather than competing below it); and the CCI investigation's discovery process may generate documentation that the NPPA could use in its overpricing computation (if the CCI investigation reveals actual transaction prices that differ from the MRPs reported to the NPPA). Practitioners advising pharmaceutical companies facing parallel CCI and NPPA proceedings must implement a coordinated litigation strategy that manages document production, privilege claims, and factual positions consistently across both forums.

## 6.2 Industry Association Activities: Price-Fixing Risk and Legal Boundaries

India's pharmaceutical industry is extensively organised through trade associations at the national level (IDMA, OPPI, FICCI Health Services) and at the state level (Gujarat-specific pharma associations). These associations provide legitimate industry advocacy functions — representing the industry before the NPPA on ceiling price revisions, before the CDSCO on regulatory guidelines, and before the Ministry of Health on drug policy issues. However, industry association activities that cross from legitimate advocacy into information exchange on

pricing, production volumes, or customer allocation create significant CCI exposure. The CCI has, in several investigations, found that pharmaceutical industry association meetings were used as forums for discussing and coordinating pricing decisions — treating the exchange of sensitive commercial information at association meetings as evidence of concerted practice even in the absence of a formal agreement. For pharmaceutical companies that actively participate in industry associations — as is standard practice for large Gujarat manufacturers — legal counsel's role includes: advising on the information that can and cannot be discussed at association forums; implementing competition law compliance programmes for association participation; and conducting periodic reviews of the association's activities to identify and correct any practices that could be characterised as information exchange on commercially sensitive matters.

**Booklet III Complete Summary:** Drug price control enforcement — NPPA's Para 19 overpricing demands, Para 20 annual ceiling violations, Para 21 extraordinary revision applications, and the CCI's parallel competition enforcement — is the price-regulation litigation that generates some of the largest financial disputes in India's pharmaceutical sector. The technical complexity of ceiling price computation, volume overcharging calculation, and interest quantification creates substantial scope for challenge that a technically competent practitioner can exploit: AIOCD data reliability, market share threshold disputes, WPI revision mechanics, and the constitutional right to carry on trade at a viable price are the legal tools that convert a seemingly straightforward NPPA demand into a contested proceeding where the final liability may be a fraction of the original demand. The CCI's competition enforcement in parallel with NPPA proceedings adds a coordination dimension that demands integrated legal strategy across both regulatory and competition law practice areas.