



Customs & Import Regulation for Pharma/Biotech:

Tariff Classification of Biologics,
SVB, Anti-Dumping &
CESTAT Strategy



Customs & Import Regulation for Pharma/Biotech

Tariff Classification of Biologics, SVB Proceedings, Anti-Dumping, Export Obligations & IPR Border Measures — The Complete Practitioner's Guide

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CHAPTER ONE

Tariff Classification of Biologics and Pharmaceutical Preparations: CTH Disputes, Heading 30.02 vs 30.04 and CESTAT Strategy

Customs Tariff Act 1975, HSN Chapter 30, Classification of Biologics, Vaccines, Blood Products and Hormones, Basic Customs Duty Differential and CESTAT Classification Jurisprudence

The tariff classification of a biologic pharmaceutical product — whether it falls under Chapter 30 heading 30.02 (blood, vaccines, toxins, cultures of micro-organisms) or heading 30.04 (medicaments consisting of mixed or unmixed products for therapeutic use) — can determine a basic customs duty differential of 5 to 10 percentage points, amounting to crores of rupees on the

large import volumes that characterise India's biologic supply chain. For a pharmaceutical importer that classifies its product under one heading (attracting the lower duty) and then faces a customs officer's reclassification into a higher-duty heading, the disputed amount — accumulated across multiple import shipments — is the most immediate and commercially significant customs legal dispute in the pharmaceutical sector. CESTAT's classification jurisprudence in the pharmaceutical sector is well-developed, and the practitioner who understands the HSN explanatory notes, the WCO classification opinions, and the CESTAT's approach to the biological vs. medicament distinction is the practitioner who delivers value in pharmaceutical customs disputes.

1.1 The 30.02 / 30.04 Distinction: The Legal Test and Its Application to Biologics

Heading 30.02 of the Customs Tariff covers human blood; animal blood prepared for therapeutic, prophylactic, or diagnostic uses; antisera, other blood fractions, and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products; cell cultures, whether or not modified; gene therapy medicinal products; human embryos. Heading 30.04 covers medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale. The critical distinction for biologic pharmaceuticals — recombinant proteins, monoclonal antibodies, biosimilars — is whether the product is classified as an "immunological product" under 30.02 (where the classification depends on the product's mechanism of action involving the immune system) or as a "medicament" under 30.04 (where the classification depends on its therapeutic use, without regard to mechanism). CESTAT has, in several decisions on recombinant proteins and monoclonal antibodies, applied the WCO classification opinion test: a product whose therapeutic effect is achieved through modulation of the immune system (blocking an immune mediator, activating an immune checkpoint, or stimulating antibody production) is an immunological product under 30.02; a product whose therapeutic effect is achieved through a non-immunological mechanism (enzyme replacement, hormonal activity, or receptor agonism) is a medicament under 30.04. For a large recombinant protein importer, the application of this test to each specific product in its import portfolio — and the preparation of a product-by-product classification analysis supported by the product's mechanism of action literature — is the foundation of the customs classification compliance and litigation strategy.

1.2 CESTAT Classification Appeals: Procedure, Precedent and Evidence Strategy

A customs classification dispute — arising from a customs officer's issuance of a speaking order reclassifying the importer's declared classification — is challenged before the Customs, Excise and Service Tax Appellate Tribunal (CESTAT) through an appeal under Section 129A of the Customs Act, 1962. CESTAT's pharmaceutical classification decisions are technically intensive: the Tribunal relies on expert evidence (including the product's prescribing information,

pharmacology literature, and WCO classification opinions) in addition to the legal analysis of the HSN headings and explanatory notes. The evidence strategy for a pharmaceutical classification appeal must include: the product's scientific monograph from the USP, BP, or Ph.Eur.; the product's approved prescribing information (package insert); pharmacology textbook references on the product's mechanism of action; and where available, a WCO classification opinion for the same or a comparable product. CESTAT is bound by Supreme Court and High Court classification precedents in the pharmaceutical sector, and the practitioner's case preparation must identify and distinguish any adverse precedents that the customs department will rely on — as well as citing favourable precedents from CESTAT's own decisions on comparable biological products.

KEY PROVISION

Rule 1, Customs Tariff (Interpretation) Rules: Classification of goods in this Schedule shall be governed by the following principles: The titles of Sections, Chapters and sub-Chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the following Rules.

1.3 Anti-Avoidance and Classification Misdeclaration: Criminal Liability Under the Customs Act

A classification dispute that the customs authorities characterise as deliberate misdeclaration — rather than a genuine legal disagreement about the applicable heading — can escalate from a civil duty dispute to a criminal investigation under Section 132 of the Customs Act (knowingly misdeclaring the description, quantity, or value of goods) and Section 135 (evasion of customs duty). The criminal provisions of the Customs Act attract imprisonment of up to 7 years for offences involving fraudulent evasion of duty above specified thresholds. For a pharmaceutical importer that has consistently declared a biologic product under one heading for several years — based on a good-faith legal view of the classification — and then faces a customs officer's retrospective reclassification covering several years of imports, the risk of the classification dispute being characterised as "misdeclaration" rather than a "bona fide dispute" is the most significant personal risk for the company's directors and customs compliance team. The practitioner's role in managing this risk includes: documenting the contemporaneous legal basis for the original classification (legal opinion, industry practice, CESTAT precedents relied upon); ensuring that the company's customs consultant filed the classification under a defensible legal position rather than a commercially motivated incorrect position; and in cases where the customs department has initiated investigation, seeking anticipatory bail protection for key personnel while the classification dispute is resolved through the civil (CESTAT) route.

Customs Valuation of Pharmaceutical Imports: Related Party Transactions, SVB Proceedings and Rule 4-9 Disputes

Customs Valuation Rules 2007, Rule 3(3) Related Party Test, Special Valuation Branch, Transaction Value Acceptance and Alternative Valuation Method Application

2.1 Related Party Valuation: The SVB Reference and Its Commercial Impact

When a pharmaceutical company imports goods — APIs, intermediates, finished formulations, or equipment — from a related party (a parent company, a subsidiary, or an affiliate that is connected to the importer through common ownership or control), the customs officer is required to examine whether the related-party relationship has influenced the transaction value declared for customs purposes. The Customs Valuation (Determination of Value of Imported Goods) Rules, 2007 provide that the transaction value between related parties is acceptable only if the importer demonstrates that the relationship did not influence the price — either through a test value comparison (showing that the related-party price is comparable to prices in sales to unrelated buyers, deductive value, or computed value) or through a close examination of the circumstances of the sale. Where the importer cannot demonstrate that the related-party price was determined at arms length, the customs officer refers the matter to the Special Valuation Branch (SVB) — a specialised customs unit that examines related-party import transactions in depth and determines whether the declared transaction value should be accepted or whether an enhanced value should be assessed. The SVB proceedings — which involve production of the importer's accounts, transfer pricing documentation, cost structure analysis, and comparable uncontrolled price comparisons — are effectively a combined customs valuation and transfer pricing audit, and the importer's position in SVB proceedings is strengthened by having a contemporaneous transfer pricing analysis (prepared for income tax purposes under Section 92D of the Income Tax Act) that demonstrates the arms-length nature of the related-party import price.

2.2 SVB Provisional Assessment and Extra Duty Deposits

Pending the SVB's determination on the acceptability of the related-party transaction value, imports are cleared on provisional assessment — with an extra duty deposit (EDD) of 1 per cent of the CIF value of each shipment maintained as security against the possibility that the SVB will enhance the assessed value. For large-volume pharmaceutical importers — whose annual imports of APIs or bulk formulations from related parties in the parent company's manufacturing network may run to hundreds of crores — the accumulated EDD can become a significant

working capital drag. CESTAT has, in several cases, ordered the release of accumulated EDDs where the SVB's determination has been unreasonably delayed (beyond the 4-month statutory timeline for SVB orders, which is frequently exceeded in practice) — providing a mechanism for importers to recover working capital where the SVB process has stalled. Practitioners advising pharmaceutical importers in SVB proceedings must: monitor the SVB timeline; file applications for finalisation of assessment where the provisional assessment has been open for more than 4 months; and where the SVB's ultimate determination enhances the transaction value, assess the CESTAT appeal prospects against the enhancement before deciding whether to pay the differential duty or pursue the appeal route.

Anti-Dumping Duties on Pharmaceutical Inputs: DGTR Investigations, Injury Analysis and Importer Response Strategy

Customs Tariff Act 1975 Section 9A, DGTR Investigation Procedure, Injury to Domestic Industry, Importer and User Industry Response, Sunset Reviews and CESTAT Challenge

3.1 Anti-Dumping Framework: Impact on Pharmaceutical Input Costs

Anti-dumping duties on pharmaceutical APIs and intermediates — imposed by India on imports from China (the dominant source of pharmaceutical inputs for Indian manufacturers) and other jurisdictions — directly affect the cost structure of Indian pharmaceutical manufacturers and their capacity to compete in regulated export markets. The Directorate General of Trade Remedies (DGTR) — India's anti-dumping investigation authority — has imposed, extended, and reviewed anti-dumping duties on a significant number of pharmaceutical APIs, including fermentation-based antibiotics, analgesics, and specialty chemicals used in pharmaceutical synthesis. For Indian pharmaceutical manufacturers that import these APIs — either because domestic supply is unavailable or because the imported material meets quality specifications that domestic suppliers cannot match — anti-dumping duties add 20 to 40 per cent to input costs, directly reducing the competitiveness of the finished formulation in regulated export markets where the Indian product must compete against Chinese and other global generics. The anti-dumping duty regime creates a recurring legal and commercial challenge: participating actively in DGTR reviews to present the user industry's (pharmaceutical manufacturer's) evidence of the duty's adverse impact on downstream competitiveness, and pursuing CESTAT challenges to DGTR methodological errors where the injury determination was based on flawed domestic industry data.

3.2 Importer and User Industry Participation in DGTR Investigations

The DGTR's investigation process — initiated on an application from a domestic producer alleging dumping and material injury — formally invites responses from importers, foreign producers, and user industries (downstream manufacturers who use the subject goods as inputs). The user industry's response to a DGTR investigation is the most effective mechanism for an Indian pharmaceutical manufacturer to protect its access to competitively priced imported APIs: by submitting a detailed questionnaire response to the DGTR demonstrating the lack of adequate domestic supply, the quality differentials between imported and domestically produced APIs, and the quantified impact of the proposed anti-dumping duty on the manufacturer's export competitiveness, the pharmaceutical manufacturer creates a documented

record that the DGTR must consider in its final determination. DGTR determinations that fail to adequately consider the user industry's evidence are vulnerable to CESTAT challenge — the CESTAT has set aside several anti-dumping duty notifications on the ground that the DGTR's injury determination did not adequately assess the countervailing impact of the duty on the user industry. Practitioners advising pharmaceutical manufacturers on DGTR participation must: obtain expert support from a trade economist to quantify the supply and competition impacts; coordinate the response with other pharmaceutical manufacturers facing the same anti-dumping risk through industry association channels; and file the questionnaire response within the DGTR's prescribed timeline (typically 30-40 days from the initiation notification) — missing the DGTR timeline forecloses participation in the investigation.

Import Licences and Drug Controller Clearance: Customs Interface with CDSCO, Import Restrictions and Port of Entry Disputes

Drugs and Cosmetics Act Import Provisions, Form 10 Import Licence, CDSCO Import Permit for New Drugs, Port of Entry Restrictions and Customs Examination of Drug Consignments

4.1 The Drug Import Licensing Framework: Form 10 and Its Conditions

Pharmaceutical products imported into India require a valid import licence under the Drugs and Cosmetics Act — specifically a Form 10 licence issued by the CDSCO (for new drugs, vaccines, and biologicals requiring central licensing) or by the State Drug Controller (for drugs that do not require central licensing). The import licence specifies: the drug's name and formulation; the source country and manufacturer; the port of entry; and any special conditions (storage, handling, or testing requirements). A consignment of pharmaceutical products that arrives at an Indian port without a valid import licence — or with a licence that does not cover the specific product in the consignment — is detained by Customs and referred to the Drug Controller at the port for inspection and licensing verification. The practical scenario of consignment detention at port — while the importer scrambles to regularise the import licence or demonstrate that the specific product is covered by the existing licence — is one of the most commercially disruptive regulatory events for a pharmaceutical importer: a temperature-sensitive biologic detained at Mumbai or Chennai port for 48 hours while documentation is regularised may be rendered unsaleable if the cold chain is broken. The importer's legal team must be able to provide emergency assistance in port detention situations: liaising with the Drug Controller's port office, preparing a legally correct import licence regularisation application, and if necessary obtaining a writ of mandamus from the High Court directing the Drug Controller to release the consignment on execution of an undertaking.

Export Obligations and Advance Authorisation: Pharma Export Schemes, EODC Disputes and DGFT Adjudication

Advance Authorisation Scheme, Export Obligation Discharge, SION for Pharmaceutical Products, EODC Applications and DGFT Demand Notice Challenge

5.1 Advance Authorisation for Pharmaceutical Exports: The SION Norm and Compliance Complexity

The Advance Authorisation (AA) scheme — under which a pharmaceutical exporter can import specified inputs (APIs, excipients, packaging materials) duty-free against a commitment to export a specified quantity of the finished pharmaceutical product within a prescribed period — is the primary export promotion mechanism for India's pharmaceutical export sector. The AA scheme's attractiveness — zero import duty on inputs, creating a significant cost advantage for the exported formulation — comes with a compliance obligation: the export obligation (a specified minimum value and quantity of the finished product to be exported within 18 months of the AA's issuance, extendable) must be discharged, and the export obligation discharge certificate (EODC) must be obtained from the DGFT to close out the AA. Export obligation disputes — where the DGFT contends that the exporter has not fulfilled its obligation and issues a demand for recovery of the customs duty saved with interest and penalties — are among the most commercially significant export compliance disputes for pharmaceutical companies. Disputes arise from: application of the incorrect SION (Standard Input-Output Norms, which specify the permissible import quantities per unit of output) to the exporter's production, resulting in the DGFT computing a larger duty-saving than the exporter actually claimed; changes in the product mix (different formulations counted differently against the export obligation); and calculation disputes about the export obligation's monetary value where invoicing was in foreign currencies that have since depreciated against the rupee.

Customs Enforcement in Counterfeit and Spurious Drug Trade: IPR Border Measures, Seizure Proceedings and Trade Mark Protection

Intellectual Property Rights (Imported Goods) Enforcement Rules 2007, Customs Trade Mark Registration, Seizure of Counterfeit Drugs at Border and Rights Holder Remedies

6.1 IPR Border Measures: The Customs Enforcement Framework

The Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007 — framed under Section 11 of the Customs Act — provide a border enforcement mechanism that enables trade mark and copyright owners to have their IP registered with the Customs authorities, so that Customs officers can detain and seize imported goods that infringe the registered rights. For pharmaceutical companies whose brand names and trade marks are being infringed by counterfeit or spurious drug manufacturers — who import or export counterfeit versions of the branded company's drugs — the Customs IPR enforcement mechanism provides a proactive border protection tool that supplements the civil court trade mark enforcement and criminal action available under the Trade Marks Act and the Drugs and Cosmetics Act. The IPR Rules require the rights holder to: register the trade mark with the Customs authorities by submitting a Form I recordation application to the Commissioner of Customs; provide detailed information about the genuine product's appearance, packaging, and distinguishing features; and deposit security to cover any potential liability for wrongful detention of genuine goods. Once registered, the Customs authorities are obligated to detain any consignment of imported goods that the officer has reason to believe infringes the registered trade mark — and to notify the rights holder, who then has the opportunity to inspect the detained goods and confirm infringement before the goods are seized. For large Gujarat pharmaceutical companies whose brands are extensively counterfeited in the domestic market and in export markets — a perennial challenge for India's large generic brands, which are frequently replicated by smaller manufacturers using similar trade names, packaging, or product appearance — the Customs IPR registration is a valuable complement to the civil enforcement strategy, creating a proactive border interception mechanism that operates before counterfeit goods enter the domestic market.

6.2 Criminal Enforcement Against Counterfeit Drugs: Section 27 and the Police-Customs Interface

The manufacture and trade in counterfeit pharmaceutical products — products that are sold under a trade mark identical or deceptively similar to a genuine manufacturer's trade mark without the manufacturer's consent — constitutes simultaneously: trade mark infringement

under the Trade Marks Act, 1999 (Section 29); manufacture of a "spurious drug" under Section 17B of the Drugs and Cosmetics Act (which defines a spurious drug as one that purports to be the product of a manufacturer by whom it is not manufactured); and potentially fraud under the Bharatiya Nyaya Sanhita. The criminal enforcement strategy against counterfeit pharmaceutical operations — raiding the clandestine manufacturing unit, seizing the stock, and prosecuting the manufacturers — is coordinated between the pharmaceutical company's private investigation team, the police (who execute the search and seizure), and the Drug Controller (who collects samples and conducts laboratory analysis). For large pharmaceutical companies that operate anti-counterfeiting programmes in Gujarat — a state with a significant pharmaceutical manufacturing cluster that also has peripheral counterfeit activity — the legal counsel's role in the criminal enforcement process includes: drafting the FIR complaint with sufficient technical specificity to establish the elements of the offence; liaising with the police investigation team during the search and seizure operation; ensuring that the Drug Controller's sampling is conducted in accordance with the Drugs and Cosmetics Rules; and representing the company as complainant in the criminal trial. The coordination between the civil trade mark enforcement (injunction and damages in the High Court) and the criminal drug enforcement (prosecution under the Drugs and Cosmetics Act) — which may involve the same counterfeit products — requires careful management to ensure consistent factual positions and effective use of evidence across both proceedings.

Booklet V Complete Summary: Customs and trade law in the pharmaceutical and biotech sector — tariff classification disputes on biologics, SVB valuation proceedings for related-party API imports, anti-dumping duty impacts on input costs, export obligation compliance under advance authorisation, and IPR border measures against counterfeit drugs — represents a practice area where the technical complexity of the subject matter (the biochemistry of the product classification, the transfer pricing analysis in SVB proceedings, the supply economics of the anti-dumping user industry response) determines the quality of the legal outcome. For Gujarat's large pharmaceutical exporters — whose US and European market revenues depend on competitive input costs, reliable export scheme compliance, and effective brand protection — these are not peripheral compliance matters but core commercial risks that demand the same level of specialist legal attention as patent and regulatory disputes.