



INDIA BRIEFING

From Dezan Shira & Associates

Issue 66 • October 2025 | www.india-briefing.com

Regulatory Standards When Selling to the Indian Market

Understanding India's Regulatory Landscape Pg 04

Sector-by-Sector Playbook for India Market Entry Pg 10

Complying with India's Customs Authorities and Managing Tax Obligations Pg 17



Introduction



ANKUR MUNJAL

Country Director
Dezan Shira & Associates
New Delhi Office

With a consumer base of over 1 billion people and a policy landscape increasingly geared towards investment, innovation, and sustainability, India represents one of the most significant growth frontiers for global businesses. Yet, its potential comes with a caveat: success in India is not determined by scale or capital alone – it is determined by how well a company navigates its regulatory environment.

Selling to the Indian market requires more than just a compelling product or competitive pricing. It demands foresight, preparation, and a compliance-first mindset. India's regulatory ecosystem is both complex and dynamic, spanning quality standards, labeling rules, import controls, tax frameworks, data protection mandates, and environmental obligations. These shape market access, brand credibility, and long-term operational resilience.

The chapters that follow in this magazine are designed to serve as a roadmap for foreign businesses planning to enter or expand in India. They unpack the nuances of India's regulatory landscape, offer sector-by-sector guidance, and explain the critical steps for customs clearance, GST compliance, and product certification.

At Dezan Shira & Associates, we support global firms in translating regulatory complexity into competitive advantage. Whether you are navigating BIS and FSSAI approvals, structuring your GST obligations, or aligning with evolving licensing norms, our experts can guide you every step of the way – from market entry planning to full-scale operational rollout. For tailored support, contact our advisors at India@dezshira.com.

With kind regards,

Ankur Munjal



DEZAN SHIRA & ASSOCIATES

www.dezshira.com



ASIA BRIEFING

www.asiabriefing.com



ASEAN BRIEFING

www.aseanbriefing.com



CHINA BRIEFING

www.china-briefing.com



INDIA BRIEFING

www.india-briefing.com



VIETNAM BRIEFING

www.vietnam-briefing.com



MIDDLE EAST BRIEFING

www.middleeastbriefing.com

Credits

Publisher - Asia Briefing
Media Ltd.

Lead Editor - Melissa Cyrill

Technical Editor - Archana Rao

Contributors - Umair Haque,
Naina Bhardwaj

Designer - Aparajita Zadoo

Regulatory Standards When Selling to the Indian Market

Contents

Understanding India's Regulatory Landscape

Pg 04

Sector-by-Sector Playbook for India Market Entry

Pg 10

Complying with India's Customs Authorities and Managing Tax Obligations

Pg 17

Annual Subscription

India Briefing Magazine is published five times a year. To subscribe, please visit www.asiabriefing.com/store. And please explore the clickable resources below.



Strategic Advisory and Commentary
info@dezshira.com



Professional Services
www.dezshira.com/services



Asiapedia
www.dezshira.com/library



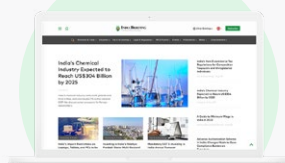
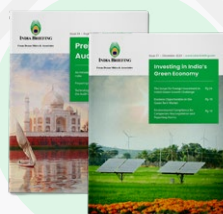
Legal, Tax, Accounting News
www.india-briefing.com/news



Magazines, Guides, Reports
www.asiabriefing.com/store



Podcast and Webinar
www.dezshira.com/library/search?type=podcast&language



Reference

India Briefing and related titles are produced by Asia Briefing Ltd., a wholly owned subsidiary of Dezan Shira Group. Content is provided by Dezan Shira & Associates.

No liability may be accepted for any of the contents of this publication. Readers are strongly advised to seek professional advice when actively looking to implement suggestions made within this publication.

For queries regarding the content of this magazine, please contact: editor@asiabriefing.com

All materials and contents
© 2025 Asia Briefing Ltd.

Asia Briefing Ltd. Unit 507, 5/F,
Chinachem Golden Plaza, 77
Mody Road, Tsim Sha Tsui East
Kowloon, Hong Kong.

Follow Us

Connect with us for the latest news, events and insights across Asia.



Like *India Briefing*
on Facebook



Follow *India Briefing*
on Twitter



Connect with *Dezan Shira & Associates* on LinkedIn



View *Dezan Shira & Associates* on Youtube



Scan the QR code to follow us on WeChat and gain access to the latest investor news and resources



Understanding India's Regulatory Landscape

India offers immense growth potential for foreign businesses, but entering the market without a strong compliance strategy can be costly. Managing regulatory standards is central to mitigating risks and enabling sustainable operations.



Archana Rao
Business Editor
India Briefing
Author

Compliance with India's regulatory standards reassures customers, partners, and authorities that a company is committed to responsible and ethical business practices. For foreign firms, demonstrating adherence to domestic quality, safety, and tax norms builds credibility in a competitive market.

Mapping India's key regulators and their mandates

Understanding the roles of different regulators is critical for ensuring compliance and gaining smooth market access.

Enabling market access and mitigating legal risks

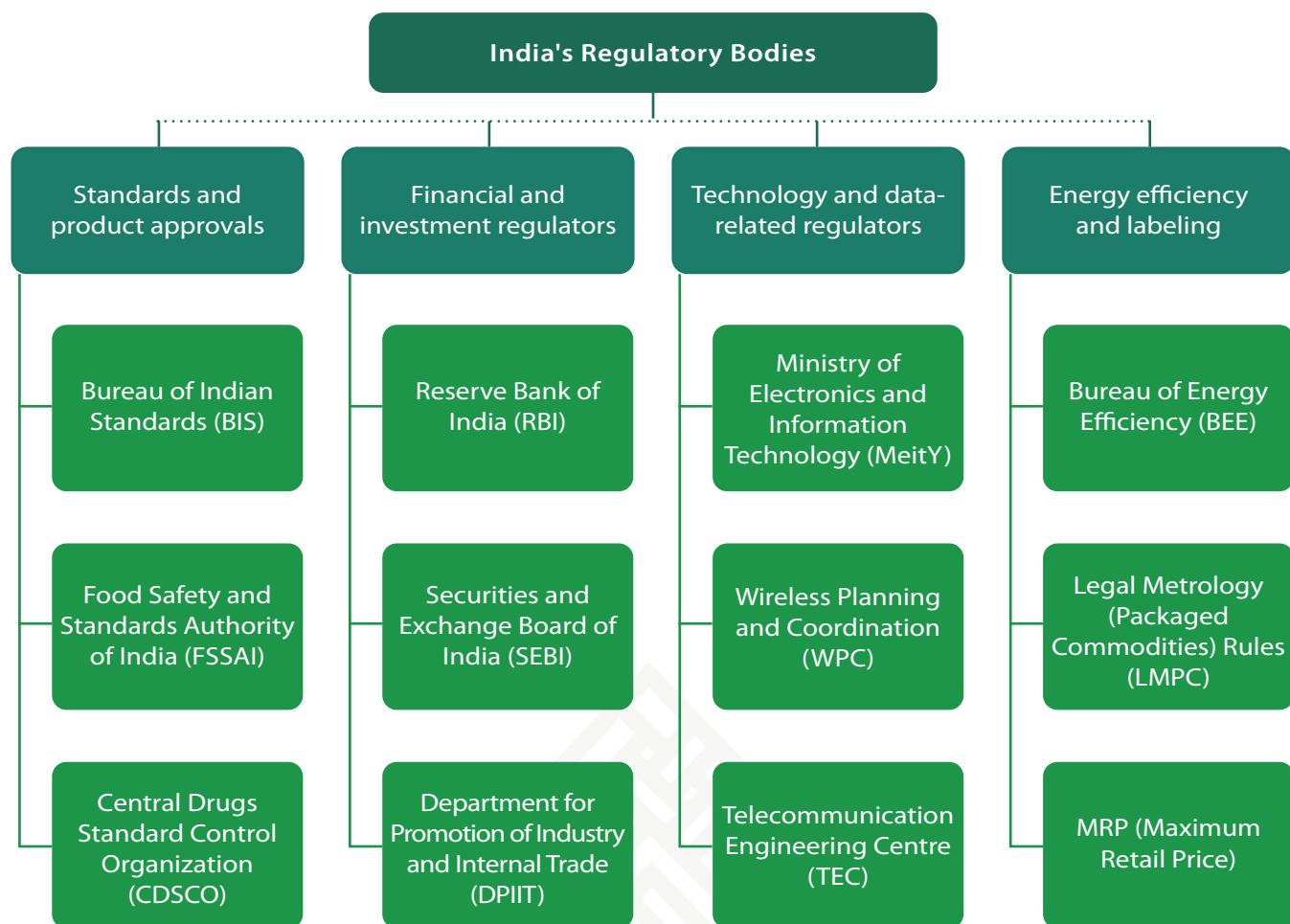
India's regulatory framework spans multiple dimensions, including corporate governance, labor laws, environmental standards, taxation (especially goods and services tax or GST), and product-specific norms such as Quality Control Orders (QCOs).

Many high-potential sectors in India, such as pharmaceuticals, food processing, financial services, and e-commerce, require multiple approvals and certifications before operations can begin. Regulatory compliance opens doors to government contracts, public procurement, and smoother import-export clearance.

1. Product standards and safety

India enforces strict product conformity requirements through specialized agencies:

- **BIS certification:** Oversees mandatory certification for electronics, consumer goods, and industrial products to ensure safety and quality.
- **FSSAI licensing:** Regulates food imports, processing, labeling, and safety compliance, making it central for FMCG and agribusiness players.
- **CDSCO approvals:** It governs pharmaceuticals, medical devices, and clinical trials, requiring rigorous approvals to protect public health.



2. Financial and investment regulations

For businesses entering India through capital markets or FDI, regulatory alignment is essential:

- **RBI:** Regulates foreign exchange, banking, and cross-border capital inflows.
- **SEBI:** Supervises securities markets, foreign portfolio investments, and ensures investor protection.
- **DPIIT:** Frames FDI policies, sectoral caps, and facilitates ease-of-doing-business initiatives.

3. Technology and data compliance

India's digital economy is overseen by multiple specialized regulators:

- **MeitY:** Issues frameworks for data protection, IT governance, and cybersecurity.
- **WPC approval:** Manages spectrum allocation and approvals for wireless and IoT devices.
- **TEC certification:** Requires testing and approval for telecom and networking equipment.

4. Energy efficiency and labeling

To align with sustainability and consumer transparency goals, businesses must comply with:

- **BEE star labeling:** Mandatory efficiency ratings for appliances and equipment.
- **LMPC registration:** Legal Metrology Packaged Commodities (LMPC) registration for weight, measure, and packaging accuracy.

- **MRP labeling:** Transparent Maximum Retail Price (MRP) labeling for all packaged goods.

5. Environmental and sustainability compliance

India enforces extended obligations for resource management:

- **EPR compliance:** Producers of plastics, batteries, and electronics must establish collection and recycling systems under Extended Producer Responsibility (EPR) mandates.

How global standards differ from Indian standards

Businesses selling into India often assume that compliance with international benchmarks, whether European, American, or Chinese, will automatically satisfy Indian regulators. This assumption can be costly. While India is steadily harmonizing many rules with global practices, significant variations remain in safety requirements, quality thresholds, and testing norms.

Navigating global labeling standards and certification in India

Global marks like CE (EU), CCC (China), or FDA approvals (US) do not replace India's mandatory certifications.

While the EU, China, US, and IEC frameworks set important international benchmarks, India requires localized compliance with bilingual labeling, statutory safety marks, and domestic testing.

International certifications can add credibility, but Indian approvals are non-negotiable.

Turning compliance into competitive advantage

Adapting to India's unique regulatory framework is about building long-term credibility with regulators, partners, and consumers. To succeed in India, foreign businesses must do the following:

1. Understand statutory authorities

- BIS/ISI certification for electronics, appliances, and industrial goods.
- FSSAI labeling for food, with bilingual text, veg/non-veg symbols, allergens, and nutrition info.
- CDSCO approvals for pharmaceuticals and medical devices.
- EPR compliance for plastics and e-waste management.

2. Localize product labeling and packaging

- Use Hindi/regional language and English bilingual labels to meet consumer protection rules.
- Adapt international labels (e.g., CE, ENERGY STAR) as supplementary, not substitutes.
- Include statutory Indian disclosures such as expiry dates, allergen warnings, and nutritional values.

3. Integrate global and Indian standards

- Combine eco-labels (EU Ecolabel, ENERGY STAR) with mandatory Indian marks to show both global responsibility and local compliance.
- Highlight this dual compliance as part of marketing to strengthen consumer trust.

Mandatory vs. voluntary product compliance

Foreign businesses entering India must navigate a

BIS Compliance in India's Retail Market: What Brands Must Know

The Bureau of Indian Standards (BIS) sets and enforces product quality norms that many retail categories must meet before sale in India. Compliance typically happens through two routes:



i. ISI Mark licensing

For products covered by Quality Control Orders (QCOs) such as toys, footwear, domestic pressure cookers, helmets, cables, and many appliances. Each factory location needs its own license. Process: application → factory audit (as applicable) batch/sample testing at BIS-recognized labs → grant of license → ongoing surveillance.

ii. Compulsory Registration Scheme (CRS)

For specified electronics and IT goods (e.g., laptops, LEDs, power banks). Manufacturers register after getting product samples tested at BIS-recognized labs; no factory audit, but strict labeling and periodic retesting rules apply.

Quick Compliance Guide



Customs blocks non-compliant imports for QCO/CRS-listed items. ISI/CRS marks, standard numbers, manufacturer/brand details, and country of origin must be correctly displayed on product and packaging.



Verify certificate scope: model variants, plant address, and validity dates.



Online listings must show certification details; platforms often de-list non-compliant SKUs.



Indian importers/brand owners are responsible for compliance, even when manufacturing is offshore.



Any design, component, or factory change can trigger retesting or license update.



Maintain test reports and traceability; plan surveillance samples.



Build a "change-management" SOP with vendors to avoid silent spec drift.

For more information, read our article "[BIS Certification in India 2025: A Comprehensive Guide for Foreign Manufacturers](#)".

For business inquiries, reach us at: India@dezshira.com

regulatory landscape that differentiates between mandatory and voluntary standards. Mandatory standards are legally binding under Indian law and enforced by sector-specific regulators, while voluntary standards allow companies to showcase higher levels of quality, safety, or sustainability.

At the core of India's mandatory regime is the BIS ISI

certification system, administered under the Bureau of Indian Standards Act, 2016. For products notified under the central government's QCOs, ISI marking is non-negotiable; only certified products can be manufactured, imported, or sold in the country.

The BIS framework covers an extensive range of industries, including construction materials,

Know the Difference between Product Labeling and Product Marking

Aspect	Product labeling	Product marking/certification
Definition	Information is provided on the product package or container to communicate details to consumers, regulators, and retailers.	Symbols, logos, or marks directly affixed to the product or the packaging to show conformity with technical or safety standards.
Purpose	Ensure transparency, consumer protection, and regulatory compliance.	Demonstrates that a product meets regulatory, safety, or environmental requirements; often linked to certification schemes.
Typical Content	- Ingredients and nutritional info (food & beverages) - Usage instructions, warnings, and safety info (chemicals, cosmetics, pharmaceuticals) - Manufacturing/expiry dates - Allergen disclosures	- Certification marks (CE, BIS, CCC, UL, FCC) - Safety or hazard symbols (flammable, recyclable, WEEE, ATEX) - Eco-labels or energy efficiency grades (EU Ecolabel, ENERGY STAR)
Examples	- India: FSSAI food labeling (nutrition facts, veg/non-veg logo) - US: FDA drug labeling (dosage, side effects) - EU: Cosmetics labeling (open-jar symbol for shelf life)	- Europe: CE marking (safety and conformity) - China: CCC mark (product safety) - India: ISI/BIS mark (quality and safety certification)

consumer goods, electronics, automotive parts, metals, food products, and medical devices.

Certification involves product testing, factory audits, and ongoing compliance verification, ensuring that goods entering the Indian market meet minimum thresholds of safety, durability, and reliability. Non-compliance exposes businesses to penalties, confiscation of goods, or even import bans.

Voluntary certifications, by contrast, are not mandated by law but are increasingly adopted by companies to differentiate on quality, enhance brand credibility, and build consumer trust. Aligning with eco-labels or international marks (such as CE or ENERGY STAR) alongside statutory Indian approvals can position businesses as both globally competitive and locally compliant.

Risks of non-compliance

Non-compliance in India carries costs beyond fines or confiscation.

- **Customs delays and costs:** Shipments may be held at ports, leading to delayed market entry and higher logistics expenses.
- **Regulatory penalties:** Companies face fines, license cancellations, or criminal liability under health, safety, and environmental laws.
- **Market access disruption:** Non-compliant products risk recalls or bans, affecting continuity of supply and customer trust.
- **Reputational fallout:** Negative publicity around safety or environmental violations damages brand equity and investor confidence.
- **Regulatory spillover:** With interlinked compliance systems, one violation can trigger scrutiny across multiple agencies, creating broader operational barriers.

Compliance as a strategic lever

Compliance with local standards forms the foundation for market access in India, but adopting global standards offers a competitive edge. Voluntary certifications like ISO 9001 or ISO 14001

Sector-Specific Regulatory Standards: Mandatory and Voluntary Compliance Requirements

Sector	Mandatory requirements (BIS/statutory)	Voluntary standards/certifications
Construction & materials	- Portland cement (IS 269, IS 1489) - White cement (IS 8042) - Structural steel (IS 2062:2011) - PVC insulated cables (IS 694)	- GreenPro certification (IGBC) - ISO 9001 for quality management
Household & consumer goods	- Pressure cookers (IS 2347:2017)- LPG cylinders (IS 3196) - Electric water heaters (IS 2082:2018) - Electric irons (IS 302)	- Energy efficiency labeling (BEE star rating) - ISO 14001 (environment management)
Electrical & electronics	- Switches & socket outlets (IS 3854) - Cables & wires (IS 694, IS 1554)- Electrical transformers (IS 1180)	- ENERGY STAR (voluntary eco-label) - IEC alignment (international safety standards)
Automotive & industrial	- Helmets (IS 4151) - Safety glass (IS 2553) - Automotive wheels & rims (IS 9438)	- AIS certification (Automotive Industry Standard, some categories voluntary) - ISO/TS 16949 (automotive quality)
Steel & metal products	- Hot rolled steel plates (IS 2062) - Galvanized plain sheets (IS 277:2003) - Steel tubes & pipes (IS 1161, IS 1239) - Aluminum alloys (IS 737, IS 733)	- ISO 50001 (energy management) - Responsible steel certification
Food & packaged goods	- Packaged drinking water (IS 14543) - Mineral water (IS 13428) - Milk powder & condensed milk (IS 1165, IS 12176)	- Organic certification (Jaivik Bharat, India Organic) - HACCP/ISO 22000 (food safety)
Pharmaceuticals & medical devices	- CDSCO approvals for drugs & devices - BIS certification for notified medical devices	- WHO-GMP certification - ISO 13485 (medical device quality systems)
Environmental compliance (cross-sector)	EPR compliance for plastics, e-waste, batteries	Voluntary eco-labels (EU Ecolabel, green seal)

Note: IS codes are Indian Standard codes developed and published by the Bureau of Indian Standards (BIS).

enhance credibility, foster consumer trust, and facilitate integration into global supply chains. For export-driven firms, these standards ease trade and anticipate future regulations.

More than a box-ticking exercise, proactive compliance strengthens resilience, reputation, and long-term growth, aligning businesses with India's evolving regulatory and sustainability priorities. 🇮🇳



AVOID COSTLY DELAYS IN MARKET ENTRY

Get step-by-step support, covering BIS certification, tax, labeling, and customs approvals designed for your industry and business model. Reach our experts for support at: India@dezshira.com.

[EXPLORE MORE](#)



Sector-by-Sector Playbook for India Market Entry

Success in India hinges on more than market potential. Companies that anticipate challenges and treat compliance as a growth enabler, not a barrier, convert complexity into competitive advantage.



Melissa Cyrill
Deputy Managing Editor
Asia Briefing
Author

India has emerged as one of the world's most attractive destinations for foreign investors and multinational corporations (MNCs). With a population surpassing 1.4 billion, a growing middle class, widespread digital adoption, and supportive reforms, the Indian market promises unparalleled scale and growth potential.

The numbers themselves are striking. India is on track to be the world's third-largest economy by 2030. Its consumption economy is expected to reach US\$6 trillion in the same period, driven by urbanization, digital penetration, and rising disposable incomes. In parallel, India's government has prioritized reforms that ease doing business – from tax simplification under the Goods and Services Tax (GST), to production-linked incentive (PLI) schemes that encourage manufacturing.

Yet, India is not a plug-and-play market. For every global company that has scaled, there are cautionary tales of firms underestimating India's regulatory environment, misjudging consumer preferences, or

falling short on compliance. A single oversight – be it in labeling, certification, or pricing – can derail a market entry strategy.

In the following sections, we examine four critical sectors – food and beverage, healthcare, pharmaceuticals, and technology – through the lens of foreign entrant challenges, regulatory hurdles, and practical compliance pathways. We also discuss cross-sector insights and highlight lessons learned from real-world scenarios.

Food and beverage sector

1. Typical foreign entrant challenges

India's F&B market was worth over US\$330 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 11.05 percent from 2024-2030 to reach nearly US\$691 billion by 2030. With around 65 percent of the population under 35, consumption patterns are youthful and experimental. Young consumers are increasingly

open to trying new cuisines, novel product formats, and premium offerings that align with their aspirations and social identity. This shift is amplified by the pervasive influence of social media, where trends, influencer recommendations, and viral food experiences rapidly shape demand and purchasing decisions. Yet, global players face unique obstacles:

- **Distribution complexity:** Unlike consolidated retail in mature markets, India remains fragmented, with a large share of retail sales still happening through mom-and-pop “kirana” stores. Distribution partnerships are critical but can be difficult to manage at scale.
- **Taste localization:** A beverage brand that works in the US may taste “too sweet” or “too bland” or “too bitter” in India. Many multinationals have had to reformulate flavors to suit regional tastes.
- **Shelf-life constraints:** Regulators impose stringent shelf-life rules, often shorter than those in global markets. Importers must plan logistics with tight time margins.
- **Price pressure:** Price-sensitive consumers, combined with competition from local brands, demand innovative packaging – smaller sachets, “value packs,” or family-sized bundles.

2. Key regulatory hurdles

The Food Safety and Standards Authority of India (FSSAI) enforces a layered compliance framework:

i. Licensing and registration:

- » All food business operators (FBOs), including importers, manufacturers, and distributors, must obtain either a state or central FSSAI license depending on turnover and scale.
- » Imported foods require an additional “Import License” tied to the importer-exporter code (IEC).

ii. Labelling and packaging rules:

- » Labels must display a green dot (vegetarian) or

brown dot (non-vegetarian).

- » Allergen declarations are mandatory. Failure to list even trace allergens may invite penalties.
- » Nutritional information must conform to Indian standards, which may differ from WHO's Codex Alimentarius or US FDA values.
- » Expiry dates must be in DD/MM/YYYY format, which often trips up foreign exporters.

iii. Additive and preservative rules:

- » Not all additives permitted internationally are approved in India. Artificial sweeteners, for example, require explicit mention on the label and may face additional restrictions.

iv. Port clearance:

- » Imported food is tested at designated FSSAI labs. Consignments remain under customs custody until clearance. Even minor deviations – like mismatched batch numbers – can delay release.

v. Advertising and claims:

- » Claims such as “sugar-free,” “fat-free,” or “organic” are tightly regulated. FSSAI has penalized firms for exaggerated claims.

3. Practical pathways to compliance

- **Pre-market label audits:** Before shipping, companies should conduct third-party label audits against FSSAI requirements. Multinationals often run “mock customs clearances” to spot errors.
- **Import logistics planning:** Build lead times into shipping schedules. Assume 2–3 weeks for lab clearance at ports. Maintain safety stock locally to avoid supply disruptions.
- **Ingredient mapping:** Cross-check ingredients against FSSAI's positive list. If an ingredient is unapproved, apply for approval before shipment rather than risk rejection.
- **Local manufacturing partnerships:** Some entrants sidestep import bottlenecks by contract-manufacturing locally under Indian compliance norms.

- **Crisis preparedness:** Develop protocols for rejected shipments. A few firms have successfully redirected rejected consignments for re-export to nearby markets (e.g., UAE).

Case Study

The FSSAI banned the import and sale of certain batches of Nestlé Maggi noodles in 2015 due to reportedly excessive lead levels and mislabeling. The case highlighted how strict enforcement can disrupt even the biggest players. Nestlé eventually relaunched after reformulation and compliance clearance – its long-term familiarity and popularity surviving the reputational test.

Learning: Even established brands must rigorously test and localize labeling/ingredients before market entry.

For executives, the lesson is that India rewards localization. Companies that succeed like PepsiCo with its Kurkure snacks or Nestlé with Maggi noodles have adapted products to Indian tastes, invested in rural distribution, and complied rigorously with the FSSAI.

Healthcare sector

India's healthcare market is projected to exceed US\$638 billion by 2025, according to an industry report, recording 17.5 percent CAGR in the last 10 years. Private sector healthcare facilities (secondary, tertiary, and quaternary care institutions) are concentrated in metros, tier-1, and tier-2 cities.

Private healthcare spending surged during and after the COVID-19 pandemic, driving the hospital market from US\$62 billion in 2020 to an estimated US\$132 billion in 2023.

The sector is among India's largest employers at around 7.5 million people. Industry watchers expect the sector to employ an additional 6+ million by 2030.

India is also a thriving medical tourism hub, with multispecialty hospitals in most major cities and metropolitan hubs, providing high quality and cost-competitive care compared to its peers in Asian and Western markets. Per an industry report, costs of medical services can be as low as one-tenth of that in the US or Europe. The low cost of clinical research has also made India a hub for R&D activities.

India permits 100 percent FDI in hospitals and medical devices under the automatic route. In FY 2023-24, Indian hospitals captured 50 percent of all FDI in the healthcare sector, amounting to approximately US\$1.5 billion. Private equity firms and global investors (for e.g., Temasek, Blackstone, Carlyle) are leading acquisitions and capital deployment in hospital chains. Hospital chains are increasingly expanding into tier-2 and tier-3 cities, and deeper into diagnostics and ancillary services.

1. Typical foreign entrant challenges

The hospital industry in India is capital-intensive, and major players reinvest earnings into capacity expansion, infrastructure, and technology. Healthcare demand is rising, especially outside metro areas, combined with the growth of medical tourism. Among the top 10 listed hospital firms in the country, planned bed capacity expansion between FY24–FY27 is ~47 percent, with emphasis on growth in northern and southern regions. Insurance penetration (public and private) is improving, creating more predictable revenue streams. Nevertheless, despite the scale of opportunity, foreign entrants can stumble due to the following factors:

- **Affordability challenge:** Consumers are highly price-conscious, while the central government caps prices of critical devices like stents.
- **Infrastructure gaps:** Large swathes of rural India lack adequate hospitals, complicating nationwide rollout of health insurance.
- **Domestic competition:** Indian manufacturers supply affordable alternatives, eroding margins.
- **Accreditation differences:** Western standards don't always match India's NABH framework.

2. Key regulatory hurdles

Healthcare products must satisfy overlapping requirements:

i. CDSCO regulation of medical devices:

- » Devices are categorized as Class A (low risk) to Class D (high risk). Approval processes escalate with class.
- » Foreign manufacturers must appoint an Authorized Indian Agent to interface with CDSCO.
- » Devices without CDSCO approval cannot be sold even if FDA or EMA approved.

ii. Price caps by NPPA:

- » Under the Drug Price Control Order, the National Pharmaceutical Pricing Authority (NPPA) caps the price of stents, implants, and certain diagnostics.
- » Price reductions can be drastic: cardiac stent prices were capped by up to 85 percent in 2017.
- » Hospitals are required to pass on capped prices to patients, not bill "service charges" to compensate.

iii. Accreditation via NABH:

- » Hospitals seeking medical tourism accreditation must comply with NABH norms.
- » Foreign device makers aiming to partner with hospitals need to align their after-sales training programs with NABH's competency requirements.

Case Study

2017 Cardiac Stent Price Cap: The NPPA slashed prices of cardiac stents by up to 85 percent, forcing companies like Abbott, Medtronic, and Boston Scientific to withdraw premium models temporarily, citing unsustainable margins.

Learning: Foreign healthcare investors must recognize that India is both a mass and a premium market. Pricing strategies must account for sudden NPPA interventions. Dual-tier models (premium for private hospitals, capped variants for public tenders) are essential.

iv. Public procurement policies:

- » Devices purchased under government tenders often require proof of Indian registration and there may be preferential treatment for "Make in India" bidders.

3. Practical pathways to compliance

- **Regulatory gap analysis:** Map US/EU dossiers against CDSCO requirements early to avoid missing modules.
- **Price modeling:** Incorporate potential NPPA caps into revenue forecasts. Some firms hedge by launching premium variants in private hospitals while offering capped models for public procurement.
- **Local agent engagement:** Select Indian agents with proven CDSCO track records. Many foreign firms mistakenly use distributors as regulatory agents – leading to conflicts of interest.
- **Hospital engagement:** Offer training packages and device usage workshops as part of product launches. NABH places high value on operator training.

- **Leverage state incentives:** Several states, such as Tamil Nadu and Telangana, offer tax breaks for med-tech parks. Locating near such clusters can ease compliance and distribution.

Pharmaceutical sector

India's pharmaceutical industry is expected to reach US\$130 billion by 2030 at a CAGR of over 10 percent and become a US\$450 billion market by 2047. Existing pharmaceutical clusters in the country benefit from government support such as via the PLI schemes and the 'Strengthening of the Pharmaceutical Industry (SPI) scheme,' which aim to boost productivity, quality, and sustainability. India also allows up to 100 percent FDI through the automatic route for greenfield pharmaceutical projects. In case of brownfield, up to 74 percent FDI is allowed via the automatic route, after which government approval is required. The period between April 2000-June 2025 saw the drugs and pharmaceuticals industry receive FDI equity inflow worth US\$24,617 million.

India hosts the largest number of USFDA-compliant plants outside the US and more than 2,000 WHO-GMP certified facilities. With over 10,500 manufacturing units supplying to more than 150 countries, the country's pharmaceutical capabilities span the full spectrum of production – from active pharmaceutical ingredients (APIs) and generics to advanced biologics.

The industry's growth is being reinforced by a rapidly expanding contract research, development, and manufacturing organization (CRDMO) segment, which is projected to double to INR 1.21 trillion (US\$14 billion) by 2028, according to Macquarie. This positions India as a critical partner for global pharmaceutical companies seeking scalable, cost-effective, and regulatory-compliant manufacturing solutions.

Complementing its drug manufacturing strength, India's medical technology (MedTech) sector is on a robust growth trajectory. As per the Confederation of Indian Industry (CII), MedTech exports are expected to reach up to US\$20 billion (INR 1.69 trillion) by FY2030, supported by innovation, rising domestic capabilities, and increasing global demand for affordable, high-quality medical devices.

1. Typical foreign entrant challenges

India's pharma industry is rapidly modernizing and benefits from both a large domestic market and exports, but still presents hurdles for global firms:

- **Patent disputes:** Indian law emphasizes access over monopoly, often curtailing patent extensions.
- **Price controls:** Many life-saving drugs are capped, reducing profitability.
- **Trial delays:** Local trials are mandatory even for globally approved drugs.
- **Local manufacturing push:** Multinationals are encouraged to build plants or contract manufacture locally.

2. Key regulatory hurdles

i. Drug approval via CDSCO:

- » Requires submission of a Common Technical Document (CTD) dossier, including clinical data.
- » Overseas clinical trial data may not be accepted unless bridged with Indian trials.

ii. Clinical trials:

- » Mandatory ethics committee approvals.
- » Audio-visual recording of patient consent is compulsory, unique to India.
- » Foreign sponsors must register trials with the Clinical Trials Registry – India (CTRI).

iii. Patent law complexities:

- » Section 3(d) of India's Patent Act restricts "evergreening" of patents. Incremental

innovations (e.g., new formulations of an old drug) are often denied protection.

- » Compulsory licensing provisions allow the government to permit generics if patented drugs are unaffordable.

iv. Drug price controls:

- » Over 400 medicines fall under the National List of Essential Medicines (NLEM).
- » NPPA revises ceiling prices annually, often reducing margins overnight.

v. Local manufacturing push:

- » Import-dependent pharma products may face delays or discouragement unless firms commit to local manufacturing under “Make in India” or PLI schemes.

3. Practical pathways to compliance

- **Parallel filing strategy:** Submit applications to CDSCO alongside FDA/EMA to compress time-to-market.
- **Portfolio balancing:** Focus not just on patented drugs, but also generics and biosimilars. India rewards scale, not just exclusivity.
- **CRO collaboration:** Work with established Indian contract research organizations for trials – this reduces cost and accelerates timelines.
- **Patent mapping:** Conduct thorough patent landscaping in India before launch. Many global patents are not recognized locally.
- **Engage NPPA early:** Consult on potential pricing frameworks to anticipate DPCO coverage.
- **Local manufacturing units:** Even small “fill-and-finish” facilities signal alignment with India’s self-reliance goals.

Executives should frame India not as a patent stronghold, but as a volume market. While Western margins may be elusive, India offers scale in generics and biosimilars. Companies like Novartis and Pfizer recalibrated their models to emphasize India as a

Case Study

2012 Compulsory License: India’s Controller General of Patents granted Natco Pharma a compulsory license for Bayer’s cancer drug Nexavar, allowing generic sale at 97 percent lower cost. This set a precedent for India prioritizing affordability over patent exclusivity.

Learning: Innovators must assume Section 3(d) and compulsory licensing risks. A strong India strategy blends patented portfolios with generics/biosimilars.

production and R&D hub, leveraging lower costs and skilled talent.

Technology sector

1. Typical foreign entrant challenges

India’s digital economy is expected to hit US\$1 trillion by 2030. Yet entrants face:

- **Data localization:** Mandates to store certain data within India.
- **Integration barriers:** Platforms must integrate with Aadhaar, UPI, and GST networks.
- **Talent churn:** Attrition in IT remains high.
- **State-level complexity:** E-commerce, labor, and tax laws vary regionally.

2. Key regulatory hurdles

i. IT Act, 2000:

- » Governs digital contracts, cybersecurity liability, and content moderation.
- » Companies must appoint a Grievance Officer in India to address user complaints.

ii. Digital Personal Data Protection (DPDP) Act, 2023:

- » Requires explicit user consent for data collection.
- » Certain categories of “sensitive personal data” must be stored in India.
- » Non-compliance penalties can reach up to INR 2.50 billion.

iii. Sectoral regulations:

- » Fintechs fall under RBI oversight, requiring compliance with KYC/AML rules.
- » E-commerce is regulated by Consumer Protection (E-Commerce) Rules 2020, mandating disclosure of sellers, return policies, and prohibiting predatory pricing.

iv. BIS certification:

- » Mandatory for hardware imports like routers, laptops, and phones.
- » Products must be tested in BIS-accredited labs within India – foreign lab reports are not accepted.

v. State-level variations for electronic hardware:

- » Data center approvals, tax incentives, and labor regulations vary by state. Karnataka and Telangana, for example, have become tech investment hubs due to streamlined processes.

3. Practical pathways to compliance

- **Data localization strategy:** Establish India-based servers or partner with local cloud providers to meet localization norms.
- **Dedicated compliance teams:** Set up local regulatory monitoring cells, particularly for fintech and e-commerce.
- **BIS pre-testing:** Send sample units for certification well before large shipments to avoid customs delays.
- **Talent retention programs:** Offer ESOPs, career growth paths, and flexible work policies to reduce attrition.
- **Staggered expansion:** Pilot services in one state before scaling nationwide to test regulatory waters.

For executives, India’s tech market is about ecosystem alignment. Firms that succeed like Amazon, Google, and Microsoft invest in local data centers, tailor offerings to Indian regulations, and engage policymakers early. Agility in policy response is the defining differentiator. 🇮🇳

Case Study

BIS certification delays: In 2020–21, shipments of laptops and Wi-Fi routers from firms like Dell, HP, and Xiaomi faced delays at Indian ports due to tightened BIS checks and import restrictions. Some goods were stranded for weeks, disrupting supply chains.

Learning: Firms must pre-certify devices locally and factor in lead times for BIS clearance before launching.



SECURE YOUR BIS CERTIFICATION IN INDIA

Ensure swift market entry and full compliance with India’s Bureau of Indian Standards (BIS). With 30+ years of Asia-wide advisory experience, we can guide you through every stage of certification and beyond.

Our Support Includes:

- BIS registration, documentation, and post-certification guidance
- Pre-entry strategy and optimal manufacturing/retail location analysis
- Regulatory audits and risk assessments
- Import clearance and customs process optimization
- Intellectual property advisory and brand protection
- Financial compliance review aligned with India regulations

Talk to our compliance experts to get started: India@dezshira.com

[EXPLORE MORE](#)



Complying with India's Customs Authorities and Managing Tax Obligations

Expanding into India's vast consumer and industrial markets demands careful navigation of import-export rules and tax regulations. Missteps here can lead to detentions, penalties, sales delays, and lasting reputational damage with regulators and customers.



Archana Rao
Business Editor
India Briefing
Author

In India, customs serve as the critical checkpoint between a product's international origin and its commercial journey into the domestic market.

The Central Board of Indirect Taxes and Customs (CBIC) collects duties and also decides the legal admissibility of goods, enforces non-tariff regulations across sectors such as food, pharmaceuticals, electronics, and plant or animal imports, and ultimately influences both the cost and speed of market entry.

Missteps at this stage, whether through misclassification, undervaluation, or missing approvals, can trigger detentions, penalties, delayed sales, and even lasting reputational damage with regulators and customers alike.

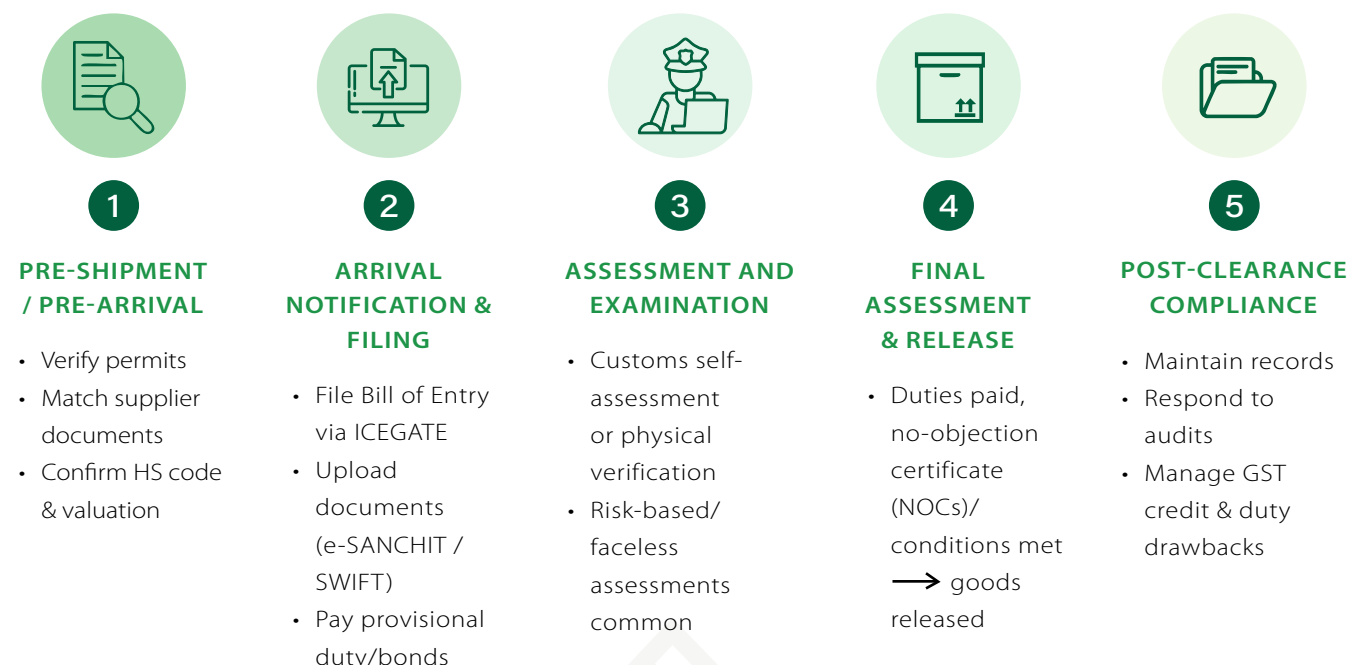
Customs authorities and import procedures

The functions of Indian customs extend across three critical dimensions.

- **Admissibility and compliance:** Customs checks that imports comply with the Customs Act, 1962, allied statutes and any Participating Government Agency (PGA) rules (e.g., FSSAI for food, Drug Controller for pharmaceuticals, Plant Quarantine for seeds/plant material).
- **Revenue collection:** Customs assesses and collects basic customs duty, cess and any applicable safeguard/anti-dumping duties; IGST and associated GST processes interact with customs clearance.
- **Trade facilitation and enforcement:** Customs enforces trade policy (quotas, licensing), intellectual property rights at the border, and anti-smuggling measures. Recent initiatives also aim to expedite legitimate trade through automation.

On the documentation front, the importer – or a licensed customs broker acting on their behalf – is responsible for submitting all supporting paperwork, including commercial invoices, packing lists, and transport documents. Where required, additional certificates from PGAs must also be provided. Increasingly, these

Key Steps in Import Declaration, Valuation, and Classification



PROCESS FLOW: PRE-ARRIVAL → ARRIVAL → CLEARANCE → POST-CLEARANCE

processes have shifted online. Systems such as e-SANCHIT and ICEGATE allow for digital submission of documents, which are linked to the Bill of Entry through Image Reference Numbers (IRNs).

Practical impact on market entrants

- Plan for PGA lead times in product approval (e.g., registration or testing) before shipment.
- Use experienced local customs brokers but retain internal oversight: declarations are the importer's legal responsibility.
- Invest in document digitization and standardized data templates.

Valuation: Methods and practical points

India follows the transaction value method as primary (price actually paid or payable for goods sold for export to India) under the Customs Valuation

Rules; where transaction value is not acceptable, sequential alternative methods apply. Adjustments (freight, insurance, assists) may be required under the rules. Mis-valuation can attract penalties, seizures and retrospective adjustments.

Classification (HS codes) and duty planning

Correct Harmonized System (HS) classification determines the tariff and whether specific restrictions apply. Even small changes in declared description can shift duty rates or trigger additional compliance (e.g., conformity certificates). Use binding rulings where classification uncertainty could materially affect landed cost. When making sourcing or pricing decisions, it is important to model the total landed cost comprehensively, i.e., factoring in customs duties, IGST, handling charges, inspection delays, and compliance-related expenses.

India’s recent digitization and single-window initiatives

India has accelerated its digital customs transformation to reduce touchpoints, speed up clearance, and centralize inter-agency approvals.

Companies should register on the ICEGATE, ensure their customs broker is enabled for SWIFT and e-SANCHIT, and confirm that their importer-of-record has an IEC and GSTN linkage.

Pre-loading documents into e-SANCHIT minimizes the need for post-arrival amendments. Mapping the specific PGAs relevant to a product, whether FSSAI, CDSCO, Plant Quarantine, or BIS, and understanding their electronic submission timelines can help avoid bottlenecks.

Maintaining clear documentation trails also allows businesses to benefit from faceless assessments and risk-based profiling, which in turn shortens the likelihood of physical inspections.

Quality control and standards: New priority for market entrants

India’s regulatory landscape is evolving rapidly, with quality and safety standards emerging as central pillars of trade policy. Over the past few years, India’s central government has issued a series of QCOs that make compliance with Indian standards mandatory across a growing list of product categories. These range from critical industrial inputs like steel and chemicals to consumer-facing goods, such as electronics, toys, and household appliances. The intent is twofold: to safeguard consumer interests and to level the playing field for domestic manufacturers competing with imports.

For foreign companies, this shift means that market entry strategies can no longer be limited to tariff calculations or distribution planning. In many cases, firms must secure BIS certification before their goods are cleared for sale. This process often requires local testing in accredited laboratories and product registration with BIS, adding both time and

India’s Recent Digitization Efforts: Streamlining Trade and Commerce		
Feature	e-SANCHIT	SWIFT
Full form	Electronic Storage and Computerized Handling of Indirect Tax Documents	Single Window Interface for Facilitating Trade
Purpose	Paperless submission and storage of customs documents	Single-window platform for regulatory clearances from multiple agencies
Function	Digitally uploads supporting documents (invoices, packing lists, licenses, certificates) for customs clearance	Integrate customs with PGAs to submit one declaration for multiple approvals
Scope	Document management for customs processing	Inter-agency coordination for regulatory approvals
Benefit	Reduces physical paperwork, speeds up verification, and minimizes delays	Streamlines clearances, reduces multiple visits to agencies, accelerates cargo release
Complementarity	Provides digital documents for verification	Uses these documents to obtain approvals across agencies efficiently

cost to the supply chain. For businesses operating on just-in-time models, failure to account for these requirements early can result in costly delays and missed opportunities.

Forward-looking firms are already integrating compliance planning into their India strategies. This includes:

- Mapping applicable QCOs for their product lines;
- Factoring in lead times for local testing and certification into production and shipping schedules; and
- Partnering with local compliance experts to manage the regulatory interface more efficiently.

Taxation and indirect tax compliance in India

Introduced in 2017, India's GST is a unified indirect tax system that streamlines business operations across states. For foreign investors, it simplifies market entry but demands strict, timely compliance to avoid disruptions.

GST compliance framework

Foreign companies entering the Indian market have several structural options. Once incorporated, such foreign companies or their subsidiaries are required to comply with India's GST framework.

GST registration requirements

Any foreign company supplying goods or services into India may fall within the scope of GST. This applies whether the supply is routed directly, through a liaison office, or via an Indian subsidiary.

A subsidiary incorporated in India must obtain GST registration once its turnover exceeds the prescribed threshold:

- Service providers: INR 2 million in most states (INR 1 million in special category states).
- Suppliers of goods: INR 4 million in most states.

Registration becomes mandatory irrespective of turnover if the subsidiary undertakes inter-state supply, engages in notified activities such as reverse charge transactions, or operates as an e-commerce operator or input service distributor. Voluntary registration is also available and may be advantageous, as it allows claiming input tax credit (ITC) and issuing GST-compliant invoices.

Applicability of GST

- For intra-state transactions, both CGST and SGST apply.
- For inter-state supplies, IGST applies.
- Imports of services from the parent company or other foreign entities are taxable under the Reverse Charge Mechanism (RCM).

Input tax credit (ITC)

The ITC mechanism helps in the seamless flow of tax credits throughout the value chain, and across boundaries of states. Firms can offset GST paid on inputs, input services, and capital goods against their tax liability, provided these are used for business purposes. However, certain restrictions apply:

- Blocked credits under Section 17(5) of CGST Act, such as GST on personal expenses, motor vehicles used for non-business purposes, or inputs used for exempt supplies, cannot be claimed.
- GST paid under RCM (e.g., management fees to the parent company) can be claimed as ITC if used for taxable activities.
- ITC is allowed only if the supplier has filed their returns and the credit reflects in the subsidiary's GSTR-2B, an auto-drafted ITC statement.

Invoicing and documentation

Firms must issue GST-compliant invoices containing key details such as:

- Supplier and recipient information, GSTIN, unique invoice number, date, description, HSN (Harmonized System of Nomenclature)/SAC (Services Accounting Code) codes, quantity, price, and tax rates.
- Goods: Invoices must be issued at or before removal.
- Services: Invoices must generally be raised within 30 days of supply.
- Exports: Invoices must carry the statement:
 - » "Supply meant for export on payment of IGST" or
 - » "Supply meant for export under bond/Letter of Undertaking (LUT) without payment of IGST."

E-invoicing and digital recordkeeping

E-invoicing is compulsory for companies with aggregate turnover above INR 50 million (as of August 2025). It applies to business-to-business (B2B) transactions, exports, and debit/credit notes, but not to business-to-consumer (B2C) transactions or special economic zone (SEZ) units. Businesses exceeding the prescribed turnover thresholds must generate invoices through government-approved portals, creating a verified digital trail for every transaction.

For global companies accustomed to different invoicing norms, aligning systems with India's e-invoicing framework often requires integration with local enterprise resource planning (ERP) or accounting software.

E-Way Bill requirements

For movement of goods, subsidiaries must comply with e-Way Bill rules. An e-Way Bill limit refers to the

minimum value threshold above which businesses in India are required to generate an electronic way bill (e-Way Bill) under the GST regime for the movement of goods. The thresholds vary by state (see table on Page 22).

Either the supplier, recipient, or transporter must generate the e-Way Bill via the GST portal.

Reverse Charge Mechanism

Where a foreign supplier is not registered under GST, the Indian buyer becomes liable to discharge the tax under the RCM. This ensures that tax revenue is preserved but can complicate commercial arrangements.

Companies must pay GST under RCM in specific cases, including:

- Import of services (management fees, consulting from the parent company).
- Certain notified services (e.g., legal services).
- Notified goods (e.g., tobacco leaves, cashew nuts).
- OIDAR (Online Information Database Access and Retrieval) services received from abroad.

Foreign companies and their subsidiaries should carefully structure contracts and pricing models to account for the additional compliance burden on their Indian counterparts, thereby avoiding disputes or hidden costs in negotiations.

GST on imports

- **Goods:** IGST is levied at the port of entry. With proper documentation (Bill of Entry), the subsidiary can claim ITC if goods are used for taxable supplies.
- **Services:** Taxed under RCM, payable by the foreign subsidiary company in India.

E-Way Bill Limits Across Different States in India

MAHARASHTRA

Intra-state limit
₹100,000

Inter-state limit
₹50,000

Certain goods exempted

RAJASTHAN

Intra-state limit
₹200,000
(same city)
₹100,000
(inter-city)

Inter-state limit
₹50,000

Exemptions: tobacco, wood, iron, steel

GUJARAT

Intra-state limit
₹50,000
(most goods)

Inter-state limit
₹50,000

No E-Way Bill for hank yarn, fabric, garments, and inter-city

WEST BENGAL

Intra-state limit
₹50,000

Inter-state limit
₹50,000

Limit reduced from INR 100,000 w.e.f. Dec 2023

TAMIL NADU

Intra-state limit
₹100,000

Inter-state limit
₹50,000

Some exemptions

BIHAR

Intra-state limit
₹100,000

Inter-state limit
₹50,000

DELHI

Intra-state limit
₹100,000

Inter-state limit
₹50,000

HARYANA

Intra-state limit
₹50,000

Inter-state limit
₹50,000

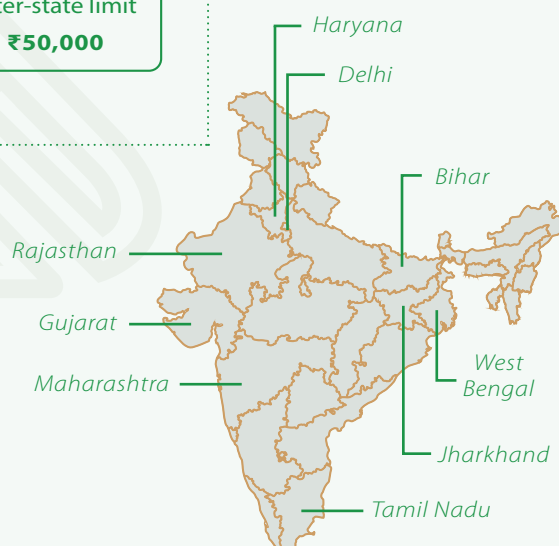
Applies to all taxable goods

JHARKHAND

Intra-state limit
₹50,000

Inter-state limit
₹50,000

Exemptions for notified goods



Accounting and record-keeping

Subsidiaries must maintain detailed records of invoices, GST returns, and related documentation for at least five years.

Cross-border transactions and special provisions

- Royalties, technical fees, and service charges paid

to the parent company attract GST (usually under RCM).

- Transfer pricing: All inter-company transactions must follow Indian transfer pricing guidelines, ensuring arm's-length pricing.
- Exports: Exports of goods and services are zero-rated, allowing refund of unutilized ITC.

Other regulatory considerations in India's market environment

- **Special authorizations and exemptions**

Certain goods, such as restricted imports, dual-use technologies, or products subject to anti-dumping duties, require special approvals or licenses from customs authorities. Subsidiaries must assess product categories in advance and obtain necessary permissions to prevent clearance delays.

- **Periodic reporting and record-keeping**

Importers and exporters are required to maintain detailed documentation, including invoices, consignment details, and customs duty payment records, for a minimum of five years. These records must be readily available for review during customs inspections or audits.

- **Consequences of non-compliance**

Under the Customs Act, 1962, mis-declaration, undervaluation, or non-compliance can result in confiscation of goods, financial penalties up to the value of the goods, and possible prosecution.

Under GST regulations, failure to generate e-way bills or providing incorrect declarations can trigger penalties equal to 200 percent of the tax evaded. In some cases, goods may also be detained during transit.

Key takeaway

Adhering to customs-related regulations alongside tax compliance is critical for foreign subsidiaries operating in India. Compliance not only safeguards businesses from financial and legal consequences but also ensures smooth supply chain operations. By maintaining transparency and regulatory

discipline, subsidiaries strengthen their credibility with Indian authorities, business partners, and investors. 🇮🇳



RELATED READING

FAQs on the Special Valuation Branch (SVB) in India: A Guide for Importers

The Special Valuation Branch (SVB) is a specialized unit within the Indian Customs Department dedicated to investigating transactions involving special relationships between importers and suppliers.

These investigations are crucial when such relationships may impact the declared value of imported goods, potentially affecting Customs Duty liability.

[READ MORE](#)

GET YOUR CUSTOM MARKET REPORT

Receive comprehensive analysis of market conditions, regulatory changes, tax and duty liability, sector analysis, and investment opportunities across Asia. Reach our experts at Dezan Shira & Associates to help your businesses make data-driven decisions with confidence. Contact us at: India@dezshira.com.

[EXPLORE MORE](#)



DEZAN SHIRA & ASSOCIATES

Your Partner for Growth in Asia



Are you making changes to your operations in Asia?

Get started by speaking to our professionals today

Accounting | Audit and Financial Review | Business Advisory | Business Intelligence
Corporate Establishment and Governance | Due Diligence | HR and Payroll | Mergers
and Acquisitions | Outbound Direct Investment | Risk Management | Tax | Technology

Our Offices in India

Delhi NCR

+91 0124 400 1785
delhi@dezshira.com

Unit No. 1101-A, 11th Floor,
Emaar Capital Tower 2, MG Road,
Near Guru-Dronacharya Metro Station
Gurugram 122002, Haryana, India

Mumbai

+91 22 4480 7040
mumbai@dezshira.com

907, Omkar the Summit,
Near Western Express Highway
Metro Station, Andheri East,
Mumbai 400093, Maharashtra, India

Bengaluru

+91 80 6185 2024
bengaluru@dezshira.com

Supreme Overseas Exports Building,
1st and 2nd Floor, Jayanagar,
7th Block, KR Road,
Bengaluru, Karnataka 560070, India

China · Hong Kong SAR · Australia · Bangladesh · Dubai UAE · Germany · India · Indonesia · Italy · Japan · Malaysia
Mongolia · Nepal · Singapore · South Korea · Sri Lanka · Thailand · The Philippines · United States · Vietnam

www.dezshira.com



Asiapedia™

