

Capability, Not Capacity

India's Critical Industries in a Fragmenting Supply Order:
Pharmaceuticals, Critical Minerals and Space

Parth Suthar
Counterfoil*

September 2026

Abstract

India has committed about Rs 4.1 lakh crore (US\$50 billion) to strategic industries just as U.S.–China rivalry has raised the value of non-Chinese supply. We argue that progress should be measured as *qualified capability*, meaning output that has passed its sector's binding technical or regulatory gate, rather than capacity announced. Point-in-time FDA records show that India's share of foreign drug inspections rose from 15 to 27 percent, while about 10 percent of Indian inspections still end in the most serious classification. Warning letters in fiscal 2026 are the highest since at least 2009. In critical minerals the gate is feedstock and radiological licensing; in space it is launch cadence. Geopolitical rent accrues only on qualified output, but dependence on Chinese inputs accrues on all of it. We close with a dated watch-list and six policy recommendations.

Keywords: industrial policy; supply-chain geopolitics; critical minerals; pharmaceutical regulation; space economy; India.

JEL: F13, F52, L52, L65, L72, O25, O53.

*Counterfoil Working Paper No. 1. Data through 21 September 2026. All figures in §4 are computed from Counterfoil's point-in-time corpus of U.S. FDA records and generated directly from the data; no number in those exhibits is entered by hand. Figures cited from secondary sources are flagged in the bibliography and have not been re-verified against primary documents. This paper is research, not investment advice. It discusses a live government tender (§5) only at the level of scheme design and says nothing about individual bidders' prospects.

Contents

Summary of findings	3
1 Introduction	3
2 A framework: capacity, qualification and dependence	5
3 The geopolitical setting, 2025–2026	6
4 Pharmaceuticals: the most measurable gate	8
4.1 Position and exposure	8
4.2 Data	9
4.3 Findings	10
4.4 Geopolitical reading	13
4.5 Can the gate be forecast?	13
5 Critical minerals and nuclear: the feedstock gate	15
5.1 One ore, two programmes	15
5.2 The magnet scheme and what it pays for	15
5.3 Geopolitical reading	16
5.4 Heavy rare earths and the price weapon	16
6 Space: capital before cadence	17
6.1 Growth	17
6.2 The gate	18
6.3 Geopolitical reading	19
7 The financing constraint common to all three	19
8 Watch-list and policy implications	19
9 Limitations	21
10 Conclusion	21
About Counterfoil	22
A Data appendix	26

Summary of findings

1. **The window is real, and dated.** Between December 2025 and June 2026 the United States enacted the BIOSECURE Act, placed WuXi AppTec on the Pentagon’s 1260H list, cut its reciprocal tariff on India to 18 percent with generic drugs at zero, and signed a critical-minerals framework with India. China’s suspension of its October 2025 rare-earth export controls expires on **10 November 2026**.
2. **India is simultaneously the hedge and the hedged.** The same de-risking that raises demand for Indian drugs and magnets exposes India’s own dependence on China. About 70 percent or more of India’s imported active pharmaceutical ingredients by value, and 85–90 percent of its imported permanent magnets by quantity, come from China.
3. **Pharmaceuticals: India’s FDA presence has grown and its failure rate has not changed.** India’s share of the FDA’s drug inspections outside the United States rose from 15.2 percent (2009–14) to 26.5 percent (2023–25). Across periods, 9–12 percent of Indian inspections ended in *Official Action Indicated* (OAI), the most serious classification. India’s rate is no better than that of other exporters outside the EU, while India’s share of FDA attention has nearly doubled. Warning letters reached a 17-year high in fiscal 2026 (27 through mid-September, against a previous peak of 23).
4. **Minerals: the gate is feedstock, not the factory.** Sales-linked incentives are 89 percent of the Rs 7,280 crore magnet scheme, so the scheme pays mostly for qualified output. But monazite, the domestic ore that carries both rare earths and thorium, is still reserved to a single state enterprise. Unless the monazite framework now in draft is resolved, domestic magnet makers will depend on imported oxide.
5. **Space: capital is arriving before cadence.** The space economy is about US\$9 billion, and there are some 440 registered space startups. But the binding gate is flight. The first private orbital launch came only in July 2026, and there is no launch cadence yet.
6. **The policy lesson is to pay on gates.** Two prominent recent industrial-policy failures (the battery-cell production incentive and the 2022 Gujarat semiconductor memorandum) failed at counterparty and partner-qualification gates that nobody tracked. Schemes should disburse against dated, independently checked milestones, and those milestones should be published.

1 Introduction

For most of the period since 1991 India’s industrial strategy sat outside geopolitics. The country specialised where its factor endowments and its regulatory history gave it an edge: generic small-molecule drugs, IT services, engineering subcontracting. It bought the rest (electronics, magnets, many chemical intermediates) from the cheapest supplier, which after 2005 was increasingly China. That arrangement ended in stages. The border crisis of 2020 was followed by restrictions on Chinese investment (Press Note 3). The pandemic exposed India’s dependence on Chinese drug

intermediates. And after 2025, trade and technology policy in both Washington and Beijing moved to treat supply chains openly as instruments of statecraft.

India’s response has been a large, fast and fragmented industrial policy. Production-linked incentives across fourteen sectors carry an outlay of Rs 1.97 lakh crore. The India Semiconductor Mission adds Rs 76,000 crore, the National Critical Mineral Mission Rs 34,300 crore including expected public sector investment, the Research, Development and Innovation fund Rs 1 lakh crore, and the rare-earth magnet scheme Rs 7,280 crore. The combined stack is about Rs 4.1 lakh crore, or roughly US\$50 billion, committed between fiscal 2021 and fiscal 2032 [Counterfoil, 2026a].

This paper asks a narrower question than “is it working?”. We ask *what should be measured to know whether it is working*, and apply the answer to three sectors where India has a plausible claim to strategic relevance: pharmaceuticals, critical minerals and nuclear fuel, and space. Our answer is that the relevant unit is not capacity (plants built, bids received, money raised, memoranda signed) but *qualified capability*. By that we mean output that has passed the gate that decides whether a foreign buyer, a regulator or physics will accept it. For a drug plant that gate is a current-good-manufacturing-practice inspection. For a magnet line it is a separated oxide and a finished magnet meeting a customer’s specification. For a launch vehicle it is a flight.

The distinction matters more in 2026 than it did in 2016. Geopolitical demand for “not-China” supply is real, but buyers pay it only for supply that qualifies. A plant that is built but fails inspection, or a magnet line running on Chinese oxide, earns none of the premium and keeps all of the dependence. The rest of the paper develops that argument formally (§2), sets out the geopolitical instruments now in force (§3), and examines each sector in turn (§§4–6). §7 turns to the financing constraint common to all three. §8 gives a dated watch-list and our policy recommendations, and §9 states what our evidence cannot show.

Our empirical contribution is concentrated in pharmaceuticals, where we can measure qualification directly. Counterfoil maintains a point-in-time corpus of U.S. Food and Drug Administration records covering inspection classifications, warning letters, import-alert listings and the current drug-establishment registry. The import-alert history is reconstructed from archived snapshots of the FDA’s own pages, which lets us describe how Indian drug manufacturing has fared at the gate that matters most for its largest export market. For minerals and space the equivalent gates have not yet produced enough events to count. There we describe scheme design and the dated events that will first produce such data.

Related work. The paper draws on three literatures. The first is the new empirical economics of industrial policy, which has moved from asking whether states should pick sectors to measuring what particular instruments do [Rodrik, 2004, Juhász et al., 2023]. Its best-identified results come from settings where a policy shifted the returns to specific activities: temporary protection and technology adoption in Napoleonic France [Juhász, 2018], and South Korea’s heavy and chemical industry drive [Lane, 2024]. We take from it the emphasis on how an instrument is designed. Our distinction between paying on capacity and paying on qualified output is a design question of that kind. The second literature treats trade and financial networks as instruments of coercion. Farrell and Newman [2019] show how states that control network chokepoints can use them against others.

Clayton et al. [2023] model how a hegemon extracts concessions through the threat of withdrawing inputs, and how targets respond by building costly domestic alternatives. Our “hedge paradox” is a reduced-form version of the target’s problem, for a country that is both a substitute for the hegemon and a buyer of its inputs. The third literature is the policy record on FDA oversight of foreign drug manufacturing. The U.S. Government Accountability Office has documented that India and China host the largest numbers of foreign drug establishments, that foreign inspections collapsed during the pandemic, and that pre-announced inspections and staffing limit what the FDA observes [U.S. Government Accountability Office, 2022, 2024, 2025]. We add a longer point-in-time series, an India–China–rest-of-world comparison of outcomes, and a reconstruction of import-alert histories that the FDA does not publish.

2 A framework: capacity, qualification and dependence

Let a sector install capacity K . Each unit passes the sector’s binding gate with probability $\pi \in [0, 1]$, so qualified output is

$$Q = \pi K. \quad (1)$$

Buyers diversifying away from a dominant incumbent (here, China) pay a premium $r(\rho)$ per unit of *qualified* output, increasing in the perceived geopolitical risk ρ of the incumbent’s supply. Suppose also that production uses an input share s sourced from the incumbent, which is cut off with probability $p(\rho)$, also increasing in ρ , at a loss D per unit of capacity. Expected sector surplus from geopolitical positioning is

$$V(\rho) = r(\rho) \pi K - p(\rho) s D K - cK, \quad (2)$$

where c is the unit cost disadvantage relative to the incumbent. Three implications follow directly.

(i) The premium scales with π , the exposure does not. An increase in geopolitical risk raises V only if $r'(\rho) \pi > p'(\rho) s D$. For a sector with low qualification rates and high input dependence, *rising tension lowers the value of its capacity*. We call this the *hedge paradox*: India is bought as a hedge against China by the same shock that exposes India’s dependence on China.

(ii) Subsidy design should pay on Q , not K . A capital subsidy $\sigma_K K$ is paid whether or not the gate is passed. A sales-linked or output-linked incentive $\sigma_Q \pi K$ is paid only on qualified output, so it selects for applicants with high private estimates of π . Where the state cannot observe π ex ante, sales-linked designs screen, and capital subsidies attract applicants whose main asset is the application. The battery-cell scheme discussed in §5 is a case in point.

(iii) Reducing s is a separate project from raising π . Import substitution at the final stage (building the magnet factory) raises K without touching s if the upstream input (separated rare-earth oxide) is still imported. The upstream gate often sits under a different regulator, and in the rare-earth case under a different ministry and a different statute.

Table 1: Calibrating the hedge-paradox threshold s/π

Sector	Qualification π	China input share s	Threshold s/π
Pharmaceuticals (2023–25)	0.91	0.70	0.77
Sintered magnets, today	≈ 0	0.93	unbounded
Sintered magnets, scheme scale ($\pi = 0.5$)	0.50	0.93	1.86
range, $\pi = 0.3\text{--}0.7$	0.3–0.7	0.93	1.33–3.10
Space	n.a.	≈ 0	≈ 0

Notes: Pharmaceutical π is one minus the Indian OAI share for FY2023–25 (Table 5); s is China’s value share of India’s API and intermediate imports [Observer Research Foundation, 2025]. The magnet s is China’s share of India’s permanent-magnet imports by quantity, FY2025 [IndraStra Global, 2025], applied to oxide as an assumption. Magnet π today reflects zero domestic sintered NdFeB output [Rare Earth Exchanges, 2026]. The scheme-scale π is illustrative. A threshold above 1 means the premium must exceed the added expected loss.

A calibration. Equation (2) gives a threshold that can be filled in with observable quantities. Rising tension raises the sector’s value only if

$$\frac{r'(\rho)}{p'(\rho) D} > \frac{s}{\pi}. \quad (3)$$

The left-hand side is the premium buyers pay for each unit of additional disruption loss the sector is exposed to. The right-hand side of (3) can be measured, and Table 1 fills it in. For pharmaceuticals, $\pi \approx 0.91$ (one minus the OAI rate, Table 5) and $s \approx 0.70$ (China’s share of API imports), so the threshold is about 0.77. Buyers must pay a premium worth roughly three-quarters of the extra expected loss that India’s own China exposure carries. For sintered magnets, domestic qualified output is currently nil, because India imports all of its sintered NdFeB [Rare Earth Exchanges, 2026]. With $\pi \rightarrow 0$ no premium clears the threshold: at present, rising tension can only lower the value of India’s magnet position. At the scheme’s intended scale, with an illustrative and generous $\pi = 0.5$ (an assumption, not an estimate), the threshold is about 1.9 on imported oxide, so the premium would have to exceed the extra expected loss. Across a range of π from 0.3 to 0.7 the threshold stays between 1.3 and 3.1, above one throughout, so the ranking of the sectors does not depend on the assumed value. For space, direct dependence on China is close to zero and the paradox does not bind. Space’s exposure is to allied export licensing, which equation (2) does not model. The calibration is coarse: π is measured among inspected sites, and s is a value share of imports rather than of inputs. But it ranks the sectors, and it shows that only in pharmaceuticals does India’s geopolitical position already pay.

Table 2 maps the framework onto the three sectors, and Table 3 collects the growth indicators the sector sections discuss. The rest of the paper fills in the rows.

3 The geopolitical setting, 2025–2026

Four families of instruments now shape the three sectors. Table 4 lists them by date because the dates are part of the analysis: several are provisional and expire or come up for review within the next eighteen months.

Table 2: Binding gates, dependence and geopolitical instruments by sector

		Pharmaceuticals	Critical minerals & nuclear	Space
Capacity sig- nal (K)		Registered FDA sites; ANDA filings; PLI plants	Magnet-scheme bids; corri- dors; mining leases	Startups; funds raised; au- thorisations
Binding gate (π)		FDA inspection outcome (NAI/VAI/OAI), warning letter, import alert	Separated NdPr oxide to spec; magnet qualification; AERB licence	Orbital launch; flight her- itage; payload performance
Input depen- dence (s)		APIs and key starting mate- rials from China, $\sim 70\%+$ of API imports by value	Magnets 85–90% of imports by quantity from China; ox- ide and heavy REEs	Rad-hard electronics and some propulsion compo- nents imported
Geopolitical instrument		BIOSECURE Act; Section 232; US–India interim deal	Chinese export controls; US–India framework; Quad initiative	FDI liberalisation; US and allied partnerships
Measurable to- day?		Yes: FDA records since 2008	Partially: scheme mile- stones only	Partially: launch record, au- thorisations

Notes: NAI, VAI and OAI are the FDA’s inspection classifications: No, Voluntary and Official Action Indicated. AERB is the Atomic Energy Regulatory Board. Dependence figures from Observer Research Foundation [2025] and Counterfoil [2026a]; see §§4–6.

The American instruments are unusually India-favourable, and provisional. BIOSECURE and the 1260H listing of WuXi AppTec put pressure on sponsors with U.S. federal exposure to move contract research and manufacturing away from Chinese companies of concern, in phases. India is the obvious large-scale alternative for small molecules and peptides. The February 2026 interim trade agreement removed the 50 percent tariff that had hung over Indian goods since August 2025, and set generic drugs at zero. But the generic exemption from the Section 232 pharmaceutical tariffs carries a one-year review. The tariff relief was explicitly tied to India’s reduced purchases of Russian oil. Both are political commitments, not treaty obligations.

The Chinese instrument is demonstrably usable and currently paused. China’s April 2025 controls showed that a licensing regime can throttle magnet supply within weeks. Its October 2025 extension would have reached products made abroad with Chinese inputs. The suspension agreed in November 2025 expires on 10 November 2026. India obtained specific relief in August 2025, but that relief was granted, and so can be withdrawn. For an Indian magnet maker running on imported Chinese oxide, the parameter $p(\rho)$ in equation (2) is a date on a calendar.

The multilateral frameworks are signals, not supply. The US–India minerals framework, the Quad initiative and Pax Silica commit parties to cooperate on finance, processing and recycling. None creates a tonne of separated oxide. Their economic value to India depends on whether they lower the cost of capital or guarantee offtake for Indian processing capacity, questions the framework texts leave open.

Table 3: Growth indicators by sector

Indicator	Earlier	Middle	Latest	Source
<i>Pharmaceuticals</i>				
Pharma exports, US\$ bn (FY23 / FY24 / FY25)	25.39	27.85	30.47	Pharmexcil
of which to the US, US\$ bn	7.55	8.73	10.52	Pharmexcil
US share, %	29.7	31.4	34.5	computed
Bulk-drug & intermediate imports, Rs '000 cr (FY20 / — / FY24)	24.2	—	37.7	ORF
of which from China	16.4	—	>27.0	ORF
FDA drug inspections of Indian sites per year (FY09–14 / 15–19 / 23–25 avg.)	103	226	267	Table 5
<i>Critical minerals</i>				
Permanent-magnet imports, '000 t (— / FY24 / FY25)	—	28.7	53.7	IndraStra
China share of quantity, % (FY25)			93	IndraStra
Sintered NdFeB: domestic output / demand est. 2030, '000 t		0	8.2	REE Exch.
Magnet-scheme target capacity, '000 t/yr			6.0	PIB
<i>Space</i>				
Registered space startups (2014 / — / Aug 2026)	1	—	~440	IDN
Private investment, US\$ m (2021–22 / — / to Mar 2026)	100.5	—	618.5	IDN
Space economy, US\$ bn (2026)			~9	IDN
Indian orbital launches per year (2015–19 / 2020–22 / 2023–25 avg.)	6.0	3.0	5.7	Table 9
Private orbital launches (to Sep 2026)			1	SpaceNews

Sources: Pharmexcil [Pharmaceuticals Export Promotion Council of India, 2025]; ORF [Observer Research Foundation, 2025]; IndraStra [IndraStra Global, 2025]; REE Exch. [Rare Earth Exchanges, 2026]; PIB [Prime Minister's Office, Government of India, 2025]; IDN [Indian Defence News, 2026]; SpaceNews [SpaceNews, 2026].

Notes: Column headings are the periods given in each row. “Permanent magnets” is a customs aggregate that includes low-value ferrite magnets. The FY2025 unit value implied by the reported total (Rs 1,744 crore for 53,700 tonnes, about Rs 325 per kg) is, on our reading, a ferrite-magnet unit value rather than an NdFeB one, so the tonnage mostly measures ferrite, and the NdFeB dependence is the 100 percent import share, not the tonnage.

4 Pharmaceuticals: the most measurable gate

4.1 Position and exposure

India is the world's largest supplier of generic drugs by volume. Pharmaceutical exports grew from US\$25.4 billion in FY2023 to US\$30.5 billion in FY2025, and the U.S. share rose from 29.7 to 34.5 percent (Table 3; Pharmaceuticals Export Promotion Council of India, 2025). Growth is increasingly concentrated in the market reached only through the FDA gate. The industry has two structural exposures that geopolitics now prices. The first is upstream: China's share of India's imports of APIs and intermediates rose from about two-thirds in 2020 to above 70 percent by value in 2023–24 [Observer Research Foundation, 2025]. Between 2019–20 and 2023–24, in the years the production-linked incentive for bulk drugs was meant to reduce that dependence, India's imports of bulk drugs and intermediates rose from Rs 24,172 crore to Rs 37,722 crore, and imports from China from Rs 16,443 crore to over Rs 27,000 crore [Observer Research Foundation, 2025]. The second is downstream: the U.S. market is reached only through FDA inspection, and an adverse outcome can close a plant's access overnight through an import alert.

The first exposure is s in equation (2). The second is π . Only the second can currently be

Table 4: Geopolitical instruments bearing on India’s critical sectors

Date	Instrument	Content	Sector
Apr 2025	China export controls (wave 1)	Licensing of seven medium and heavy rare earths and related magnets	Minerals
Aug 2025	China–India	Curbs on magnets, fertiliser and tunnel-boring machines to India lifted during Wang Yi visit [Trading Economics, 2025]	Minerals
Oct 2025	China export controls (wave 2)	Five further elements; extraterritorial rules on foreign products using Chinese inputs	Minerals
Nov 2025	China suspension	Wave-2 controls suspended until 10 Nov 2026 after US–China meeting [CIRS Group, 2025]	Minerals
18 Dec 2025	BIOSECURE Act (FY26 NDAA)	Restricts US procurement from and grants to “biotechnology companies of concern” [Ropes & Gray, 2026]	Pharma
7 Feb 2026	US–India interim trade deal	Reciprocal tariff cut to 18% from 50%; zero on generic drugs; tied to reduced Russian oil purchases [Business Today, 2026]	Pharma, all
20 Feb 2026	Pax Silica	India joins US-led trusted-technology supply-chain initiative [All India Radio News, 2026]	All
2 Apr 2026	Section 232 pharma tariffs	100% on patented drugs (20% with US onshoring); generics exempt, subject to one-year review [India Briefing, 2026]	Pharma
26 May 2026	US–India minerals framework; Quad initiative	Cooperation across mining, processing, recycling; Quad to mobilise up to US\$20bn [U.S. Embassy and Consulates in India, 2026, Al Jazeera, 2026]	Minerals
8 Jun 2026	DoD 1260H list	WuXi AppTec added, making it a company of concern under BIOSECURE [FDA Law Blog, 2026]	Pharma

Notes: Dates are announcement or enactment dates. Wave-1 and wave-2 content from Center for Strategic and International Studies [2026] and CIRS Group [2025].

measured at plant level, so the remainder of this section concentrates on it.

4.2 Data

We use four sources, all held as dated, immutable snapshots; definitions are in Appendix A.

1. *Inspection classifications* from the FDA Data Dashboard [U.S. Food and Drug Administration, 2026a]: every FDA inspection with a posted classification, by firm establishment identifier, fiscal year (October–September), product type and outcome. We keep product type “Drugs”: 4,737 Indian, 5,976 Chinese and 342,356 global records across all product types before filtering.
2. *Compliance actions* from the same dashboard: warning letters and injunctions by fiscal year and country.
3. *Import Alert 66-40*, the FDA’s list of foreign drug firms whose products are detained without physical examination for GMP failure [U.S. Food and Drug Administration, 2026c]. The FDA publishes only the current list, so we reconstructed historical listing and removal dates from Internet Archive captures back to 2009.
4. *The drug-establishment registry* [U.S. Food and Drug Administration, 2026b]: all currently

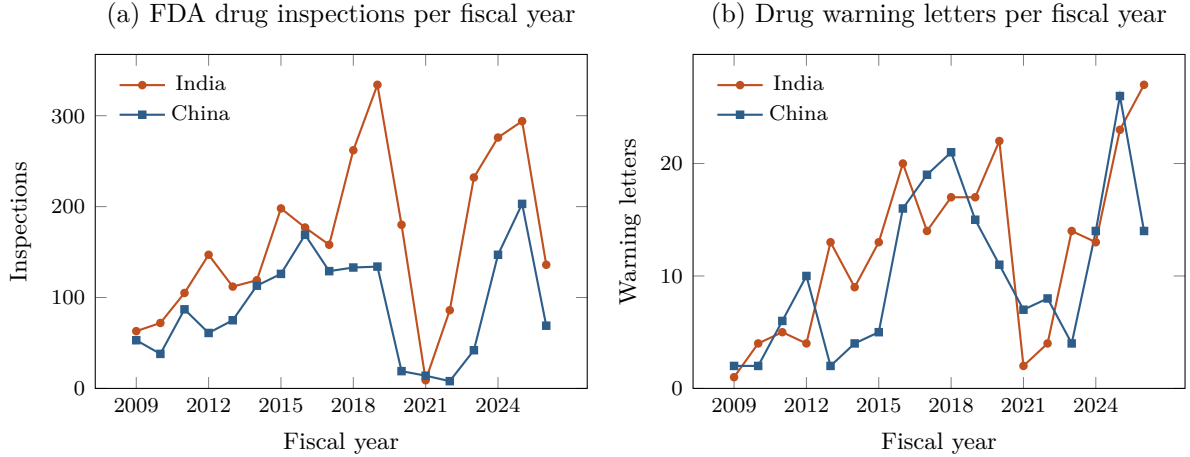


Figure 1: FDA oversight of Indian and Chinese drug manufacturing, FY2009–FY2026

Notes: FDA fiscal years run October to September. FY2026 is partial, covering records posted up to the corpus retrieval date in September 2026; inspection classifications are posted with a lag, so the FY2026 inspection count is incomplete. Warning letters are those classified by FDA with product type “Drugs.” *Source:* FDA Data Dashboard [U.S. Food and Drug Administration, 2026a]; Counterfoil corpus.

Table 5: FDA drug inspection outcomes by origin and period

Period (FY)	India			China			Rest of world, ex-US		
	<i>N</i>	<i>NAI</i> %	<i>OAI</i> %	<i>N</i>	<i>NAI</i> %	<i>OAI</i> %	<i>N</i>	<i>NAI</i> %	<i>OAI</i> %
2009–2014	618	33.0	9.7	427	35.1	7.5	3,034	46.7	3.4
2015–2019	1,129	37.3	11.0	691	28.2	15.9	3,544	40.8	4.0
2020–2022	275	40.4	12.4	41	39.0	12.2	924	27.4	4.4
2023–2025	802	37.8	9.4	392	39.3	5.9	1,827	34.2	4.6
2026 (partial)	136	39.7	11.8	69	46.4	10.1	254	49.2	6.3

Notes: Drug-product inspections with a posted classification. *VAI* share is the residual. Rest of world excludes the United States and records without a country code. FY2026 is partial. *Source:* FDA Data Dashboard; Counterfoil corpus.

registered Indian drug establishments, geocoded to postcode (1,062 establishments).

The three inspection outcomes are ordered. *NAI* means no objectionable conditions. *VAI* means objectionable conditions not warranting regulatory action. *OAI* means regulatory action is recommended. *OAI* is the event that precedes warning letters and import alerts.

4.3 Findings

Four facts stand out from Figure 1 and Tables 5 and 6.

1. India’s weight in foreign FDA oversight has nearly doubled. India accounted for 15.2 percent of FDA drug inspections outside the United States in 2009–14 and 26.5 percent in 2023–25, the last complete period (Table 6). Fiscal 2026 to date shows 29.6 percent, on records still being posted. Indian volume recovered from the pandemic much faster than Chinese. In 2020–22 China’s share fell to 3.3 percent, reflecting the near-cessation of FDA travel to China, and it had recovered

Table 6: India’s weight in foreign FDA drug oversight

Period (FY)	Share of ex-US drug inspections (%)		Drug warning letters		New IA 66-40 listings, India
	India	China	India	China	
2009–2014	15.2	10.5	36	26	40
2015–2019	21.0	12.9	81	76	38
2020–2022	22.2	3.3	28	26	18
2023–2025	26.5	13.0	50	44	26
2026 (partial)	29.6	15.0	27	14	8

Notes: Import Alert 66-40 listings are counted by the calendar year of the FDA’s published listing date, or of the first archived capture where no date is published. 130 Indian firm-listings are observed in total, of which 92 remain listed at the last capture. Only 2 spells are left-censored (already listed, with no published date, at the first capture). *Source:* FDA Data Dashboard; FDA Import Alert 66-40 via Internet Archive; Counterfoil corpus.

only to 13–15 percent by 2023–26. In inspection terms the “China plus one” shift in regulated pharmaceutical supply has already happened. India is the “one”.

2. The qualification rate has not moved. The share of Indian inspections classified OAI was 9.7 percent in 2009–14, 11.0 percent in 2015–19 and 9.4 percent in 2023–25 (Table 5), while average annual volume more than doubled. The first and last of these periods are statistically indistinguishable ($z = 0.2$). The early spike in the yearly series (19–22 percent in FY2013–14) coincided with the FDA’s data-integrity campaign against several large Indian manufacturers and has not recurred at that level. Three checks address the concern that the aggregate reflects which sites the FDA chose to inspect rather than how the sites performed (Table 8).

- *Composition.* First-time inspections of a site end in OAI less often than repeat inspections. Their share of Indian inspections rose from 33 to 37 percent between 2015–19 and 2023–25, which would pull the aggregate down. The repeat-inspection rate, the cleaner measure of established capacity, was 11.3 percent and then 10.3 percent, with overlapping intervals.
- *Within-site.* Among the 399 Indian drug sites inspected in both 2015–19 and 2023–25, the OAI rate was 7.7 percent (95% interval 6.0–9.9) in the first period and 10.4 percent (7.9–13.5) in the second. Counted by site rather than by inspection, so that frequently inspected sites carry no extra weight, the share of these sites with any OAI was 11.8 percent and then 11.0 percent (35 sites moved out of OAI, 32 moved in). The same plants did not improve.
- *Comparison group.* Under the U.S.–EU and U.S.–UK mutual recognition agreements, and the 2023 agreement with Switzerland, the FDA relies on those regulators’ inspections for most of their human-drug sites. Sites in these countries had low OAI rates even before the agreements took effect (2.8 percent in 2009–14, on 1,927 inspections), and since then the FDA’s own inspections there have also become a selected residual. Either way they are the wrong benchmark for India. Against exporters outside those agreements, India’s 2023–25 rate (9.4 percent) is indistinguishable from theirs (8.8 percent; ratio 1.1, $z = 0.3$).

India is therefore not an outlier among non-EU suppliers. It is a typical non-EU supplier whose

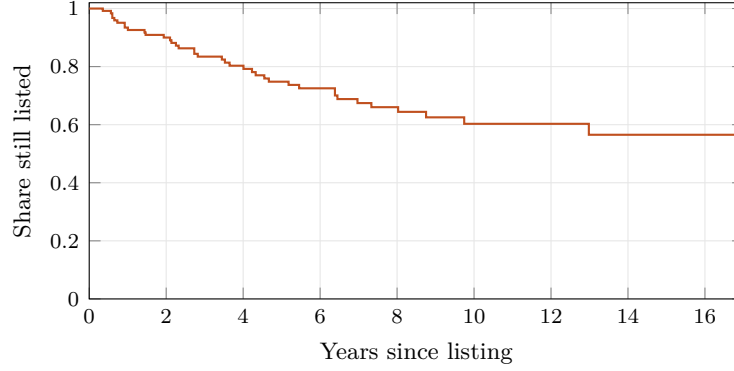


Figure 2: Time on FDA Import Alert 66-40, Indian firms (Kaplan–Meier)

Notes: $N = 130$ firm-listings, of which 38 end in removal. Entry is the FDA’s published listing date. Exit is the midpoint of the interval between the last archived capture showing the firm and the first capture without it. Firms still listed are censored at the last capture (September 2026). *Source:* FDA Import Alert 66-40 via Internet Archive; Counterfoil corpus.

share of FDA oversight has nearly doubled. In the language of equation (1), India’s π is stable at the non-EU norm and has not converged towards the EU’s.

3. Warning letters hit a 17-year high, and the cause is partly FDA practice. Indian drug warning letters numbered 27 in fiscal 2026 through mid-September, more than any full year since FY2009 (previous peak 23, fiscal 2025; Figure 1b). This does not show that escalation has become tougher. Warning letters per OAI inspection were 0.60–0.67 in every complete period except the pandemic years (Table 8, Panel C). The FY2026 figure is inflated by OAI classifications that have not yet been posted. The more likely driver is a change in how the FDA inspects. On 6 May 2025 it announced an expansion of unannounced foreign inspections, building on a pilot that began in India in March 2022 [Sidley Austin, 2025, Moneycontrol, 2026]. Unannounced inspections find what announced ones allow firms to tidy away, so a rise in findings partly measures the removal of that advantage. The result is a harder test for Indian plants, not evidence that they have become worse.

4. Exclusion is persistent. Of the 130 Indian firm-listings on Import Alert 66-40 we observe since 2009, 92 remain listed. Figure 2 treats time on the alert as a duration, right-censoring firms still listed at the last capture. An estimated 93 percent of listings last beyond one year, 75 percent beyond five and 60 percent beyond ten. The median duration is not reached within the observation window. Among the 38 listings that did end, the median time on the alert was 3.4 years. Time on the list is not the same as time excluded, because a firm that closes or abandons the U.S. market never applies for removal. By approximate name matching, only about 36 of the 92 still-listed firms have a currently registered FDA establishment, against about 22 of the 38 that were removed. Figure 2 therefore mixes exclusion and exit, and both are outcomes of the gate. For a firm that stays in business, removal takes years: the median among those removed was 3.4 years. This asymmetry (a clean inspection is a non-event, a failed one is a multi-year exclusion) is why the gate, not the capacity, governs value.

Table 7: Currently registered Indian FDA drug establishments by state

State	Establishments	Share (%)
Telangana	255	24.0
Gujarat	206	19.4
Maharashtra	169	15.9
Andhra Pradesh	130	12.2
Karnataka	91	8.6
Tamil Nadu	48	4.5
Madhya Pradesh	33	3.1
Himachal Pradesh	27	2.5
All other states and unresolved	103	9.7
Total	1,062	100.0

Notes: Establishments in the FDA drug-establishment registry with an Indian address, geocoded to postcode. Includes manufacturers, repackers and testing laboratories. *Source:* U.S. Food and Drug Administration [2026b]; Counterfoil corpus.

Geography. Regulated capacity is concentrated. Four states (Telangana, Gujarat, Maharashtra and Andhra Pradesh) hold 72 percent of registered establishments (Table 7). Telangana and Andhra Pradesh together account for more than a third. This concentration is itself a resilience question, because the same few state-level pollution, power and water regimes govern most of India’s FDA-facing output.

4.4 Geopolitical reading

The BIOSECURE shift and the Section 232 exemption for generics act on different parts of the industry. BIOSECURE rewards contract research and manufacturing organisations able to take work from WuXi. That work is disproportionately innovative, small-molecule and peptide, with sponsors who audit intensively, so the relevant π is not the average but that of the top decile of Indian sites. The generic exemption protects India’s volume business, but it is reviewable. The United States’ stated aim of onshoring production means the exemption is best read as a transition period. Out-licensing of Indian innovative assets, such as the Ichnos Glenmark Innovation agreement with AbbVie (US\$700 million upfront, US\$1.925 billion total; AbbVie, 2025), shows a third route that is less exposed to tariffs on physical goods.

None of these routes reduces s . An Indian contract manufacturer that replaces WuXi for a U.S. sponsor while buying its key starting materials from China has replaced one China exposure with an indirect one. Buyers applying BIOSECURE logic will eventually ask this question of their suppliers’ suppliers. The upstream gate is chemical synthesis capacity for key starting materials, and it remains largely unbuilt despite the bulk-drug incentive.

4.5 Can the gate be forecast?

If qualification is the relevant state variable, a natural question is whether it can be predicted before the regulator acts. Counterfoil tested this directly. A model of FDA escalation for Indian

Table 8: Robustness of the Indian OAI rate: uncertainty, comparison group, composition and escalation*Panel A. OAI share, percent [95% Wilson interval], and N*

Period (FY)	India		China		MRA countries		Other ex-US	
	OAI	N	OAI	N	OAI	N	OAI	N
2009–2014	9.7 [7.6, 12.3]	618	7.5 [5.4, 10.4]	427	2.8 [2.1, 3.6]	1,927	4.5 [3.4, 6.0]	1,040
2015–2019	11.0 [9.3, 12.9]	1,129	15.9 [13.4, 18.8]	691	2.0 [1.5, 2.7]	2,204	5.6 [4.4, 7.0]	1,166
2020–2022	12.4 [9.0, 16.8]	275	12.2 [5.3, 25.5]	41	1.5 [0.8, 2.7]	673	12.6 [8.9, 17.6]	222
2023–2025	9.4 [7.5, 11.6]	802	5.9 [3.9, 8.7]	392	2.0 [1.3, 2.9]	1,175	8.8 [6.7, 11.5]	556
2026 (partial)	11.8 [7.4, 18.3]	136	10.1 [5.0, 19.5]	69	2.1 [0.7, 5.9]	145	8.5 [4.4, 15.9]	94

Panel B. India: first versus repeat inspections of a site

Period (FY)	First inspection		Repeat inspection		First share %
	OAI % [95% CI]	N	OAI % [95% CI]	N	
2015–2019	10.3 [7.7, 13.8]	377	11.3 [9.2, 13.8]	752	33
2020–2022	4.9 [1.9, 11.9]	82	15.5 [11.1, 21.3]	193	30
2023–2025	7.8 [5.3, 11.4]	295	10.3 [7.9, 13.2]	507	37
2026 (partial)	10.2 [4.7, 20.5]	59	13.0 [7.2, 22.3]	77	43

Panel C. India: warning letters per OAI inspection

Period (FY)	Warning letters	OAI inspections	Ratio
2009–2014	36	60	0.60
2015–2019	81	124	0.65
2020–2022	28	34	0.82
2023–2025	50	75	0.67
2026 (partial)	27	16	1.69

Notes: Drug-product inspections with a posted classification, excluding the United States. MRA countries are the EU-27, the United Kingdom and Switzerland, whose inspections the FDA recognises for most human-drug sites. A first inspection is the site’s first appearance in the FDA record from FY2009, so Panel B starts in FY2015 to allow a history to accumulate. Panel C compares letters and OAI inspections dated in the same period; OAI classifications for FY2026 are still being posted, which inflates the FY2026 ratio. *Source:* FDA Data Dashboard; Counterfoil corpus.

drug sites, trained on inspection history, Form 483 observation text and firm-group records and evaluated out of fold, reached an area under the ROC curve of 0.696 (95% interval 0.658–0.733). Its top-decile precision was 27 percent against a 9 percent base rate [Counterfoil, 2026b]. The signal is real but modest, and it missed a pre-committed threshold of 0.70. For policy the implication is that qualification risk is partially forecastable from public records. A regulator, lender or buyer could therefore price it, rather than treating each plant’s compliance state as news.

5 Critical minerals and nuclear: the feedstock gate

5.1 One ore, two programmes

India’s rare-earth ambitions and its nuclear programme share an ore. Monazite, found in the beach sands of Andhra Pradesh, Odisha, Tamil Nadu and Kerala, contains roughly 55–60 percent rare-earth oxides and 8–10 percent thorium oxide [Farmonaut, 2026]. India holds about a quarter of the world’s thorium, with monazite reserves estimated at 12–15 million tonnes [Farmonaut, 2026]. Thorium is the fuel of the third stage of India’s three-stage nuclear programme. The light rare earths in the same ore, above all neodymium and praseodymium (NdPr), are the inputs to sintered NdFeB magnets for electric motors, wind turbines, electronics and defence systems.

Because monazite is radioactive, its mining and processing have been reserved to the state enterprise IREL (India) Limited under the Department of Atomic Energy. The March 2025 amendment to the Mines and Minerals (Development and Regulation) Act opened rare-earth exploration and mining to private firms but left the monazite reservation intact. A framework for limited private access is being drafted, with the most discussed option a tightly licensed opening of coastal monazite sands [Discovery Alert, 2026]. The draft faces organised opposition. Any private processor would in any case need Atomic Energy Regulatory Board approval, which typically adds 18–24 months to a standard mining permit [Discovery Alert, 2026].

5.2 The magnet scheme and what it pays for

The Union Cabinet approved the Scheme to Promote Manufacturing of Sintered Rare Earth Permanent Magnets in November 2025 [Prime Minister’s Office, Government of India, 2025]. Its main features:

- outlay of Rs 7,280 crore, of which Rs 6,450 crore is sales-linked over five years and Rs 750 crore is capital subsidy;
- target capacity of 6,000 tonnes per year of sintered NdFeB, across five beneficiaries of up to 1,200 tonnes each;
- global tender issued 20 March 2026, bids closed 12 August, technical bids opened 13 August 2026, with 20 bids received [DD India, 2026a]. The award was pending when this paper went to press.

In the terms of §2, the scheme is well designed: 89 percent of the outlay is paid on sales, that is on πK rather than K . The contrast with the advanced-chemistry-cell battery scheme is

instructive. That Rs 18,100 crore programme allocated 50 GWh in March 2022. It then had to withdraw 20 GWh from an allocatee whose relationship to the manufacturer it was trading under did not hold, and four years on stands at about 2.8 percent of target [Down To Earth, 2026a]. The failed gate there was counterparty identity, checked too late. The 2022 Gujarat semiconductor memorandum (Rs 1.54 lakh crore) failed at a different gate, partner qualification: the technology partner withdrew in July 2023 [Business Standard, 2023].

What the magnet scheme does not do is reduce s . It covers the chain from oxide to magnet, but the separated NdPr oxide must come from somewhere. China produced 94 percent of the world’s sintered magnets and 91 percent of its refined rare-earth output in 2024 [International Energy Agency, 2025], and has supplied 85–90 percent of India’s permanent-magnet imports by quantity in recent years [Counterfoil, 2026a, The Core, 2026]. A magnet line in Andhra Pradesh running on Chinese oxide carries the same exposure to the 10 November 2026 expiry as a magnet imported whole. It simply carries it one stage earlier.

5.3 Geopolitical reading

The domestic feedstock route runs through IREL’s processing capacity, including a 10,000-tonne-per-year monazite processing plant at Gudur in Nellore district scheduled for commissioning in 2026 [Wikipedia, 2026a], and through the monazite framework. The imported non-Chinese route runs through the partnerships of 2026: the US–India framework, the Quad’s proposed US\$20 billion, and bilateral arrangements with resource holders. The National Critical Mineral Mission (Rs 16,300 crore of public expenditure plus an expected Rs 18,000 crore from public-sector enterprises) and the rare-earth corridors announced in the February 2026 budget [Down To Earth, 2026b, Geopolitical Monitor, 2026] fund both routes. Neither route yet produces oxide at scale.

The nuclear side of the same ore is now on a different statutory footing. The SHANTI Act, passed in December 2025, repealed the Atomic Energy Act 1962 and the Civil Liability for Nuclear Damage Act, and opened nuclear generation to private participation under the regulatory authority of the AERB [S&R Associates, 2025]. The Nuclear Energy Mission (Rs 20,000 crore) targets at least five Indian-designed small modular reactors by 2033 and 100 GW of capacity by 2047 [World Nuclear Association, 2026]. Opening nuclear power to private firms and opening monazite to private processors are two ends of the same question. It would be coherent to settle them together, and the current sequencing does not.

5.4 Heavy rare earths and the price weapon

Two further constraints sit outside the magnet scheme’s design. The first is heavy rare earths. Sintered NdFeB magnets for traction motors, wind turbines and defence systems must keep their performance at high temperature, which requires small additions of dysprosium and terbium. These two elements were among the seven medium and heavy rare earths placed under Chinese export licensing in April 2025 [Center for Strategic and International Studies, 2026]. Monazite is overwhelmingly a light-rare-earth ore, so even a fully opened domestic monazite chain would supply NdPr but not the heavy elements. In 2026 India’s vehicle makers asked the government to defer

localisation requirements for traction motors, from 1 September 2026 to 1 April 2027, citing licensing delays and supply uncertainty for dysprosium, terbium and magnets [Rare Earth Exchanges, 2026]. The magnet scheme’s heavy-rare-earth supply is therefore an import dependence in its own right, with s close to one. It needs either non-Chinese sources through the 2026 frameworks or reduced-heavy-rare-earth magnet grades.

The second is price. An incentive paid on sales rewards qualified output, but it also exposes the recipient to the market price against which those sales are made, and China sets that price. China makes 94 percent of the world’s sintered magnets [International Energy Agency, 2025], against a scheme target of 6,000 tonnes a year, and cheap Chinese supply is widely blamed for the closure of India’s own magnet production over the past two decades [IndraStra Global, 2025]. The customs data are consistent with continued price pressure: permanent-magnet import tonnage nearly doubled in FY2025 while import value rose only modestly [IndraStra Global, 2025]. That aggregate is dominated by ferrite magnets (Table 3, notes), so it is suggestive rather than conclusive for NdFeB. In the model, a price cut lowers the effective premium r without any change in export controls. It is a coercive instrument that needs no licence and leaves no legal trace, and the scheme’s sales-linked design, the right one against weak applicants, is exposed to it. Two responses fit the framework: a price floor or contract-for-difference on qualified domestic output, or offtake commitments from the 2026 partner frameworks priced on a non-Chinese benchmark.

The dated gates. Three events in the coming months will reveal the sector’s π and s : the magnet-scheme award and its first milestone disbursements; the commissioning of IREL’s Gudur plant; and the notification of the monazite framework. China’s decision on 10 November 2026 sets the external value of all three.

6 Space: capital before cadence

6.1 Growth

India’s space economy is estimated at about US\$9 billion, with official projections of US\$40–45 billion over the next decade [Indian Defence News, 2026]. Registered space startups rose from one in 2014 to about 440 by August 2026. Reported private investment rose about six-fold, from US\$100.5 million in 2021–22 to US\$618.5 million by March 2026 [Indian Defence News, 2026]. A different count puts the sector’s trailing-year raise at US\$871 million [Business Standard, 2026b]. The difference reflects definitions (calendar versus fiscal windows, inclusion of debt and of announced-but-unclosed rounds), and is itself evidence that the sector lacks a standard ledger.

The policy scaffolding is substantial. The February 2024 FDI liberalisation allows 74 percent foreign ownership automatically for satellite manufacturing and operations, 49 percent for launch vehicles and spaceports, and 100 percent for components. IN-SPACe, the authorising body, had issued 113 authorisations to 52 non-government entities by mid-2026, and brokered 71 transfers of ISRO technology to industry by January 2026 [DD India, 2026b]. At the frontier, Skyroot became India’s first space-technology unicorn in May 2026. Pixxel has its full Firefly constellation in orbit. AgniKul flew a single-piece 3D-printed engine and received the first Indian state-government equity

Table 9: Indian orbital launches by year and vehicle, 2015–2025

Year	PSLV	GSLV	LVM3	SSLV	Total	Failures
2015	4	1	0	0	5	0
2016	6	1	0	0	7	0
2017	3	1	1	0	5	1
2018	4	2	1	0	7	0
2019	5	0	1	0	6	0
2020	2	0	0	0	2	0
2021	1	1	0	0	2	1
2022	3	0	1	1	5	1
2023	3	1	2	1	7	0
2024	3	1	0	1	5	0
2025	1	2	2	0	5	1
Total					56	4

Notes: Orbital launch attempts from Sriharikota, counting partial failures as failures. 2026 to date (partial) includes at least PSLV-C62 (failed, January), Skyroot’s Vikram-1 (the first private orbital launch, July) and GSLV-F17 (September). Counts are from the vehicle launch lists; the 2015 row was reconciled against ISRO’s mission page and the 2025 row against news reports (five launches, one failure). *Sources:* Wikipedia [2026b]; Indian Space Research Organisation [2026].

stake in a space startup (Rs 25 crore from Tamil Nadu). Digantara launched a space-surveillance sensor network [Forbes India, 2026].

6.2 The gate

Space is the sector where capacity signals are most abundant and qualification signals scarcest. Funding rounds, authorisations and memoranda are capacity (K). The gate (π) is flight, and specifically *cadence*: a launch provider is qualified for commercial customers by a record of repeated successful launches on schedule, not by one demonstration. Satellite and payload makers are qualified by flight heritage. On 18 July 2026 Skyroot’s Vikram-1 became the first Indian private rocket to reach orbit, deploying customer payloads to a 450-km orbit [SpaceNews, 2026]. That is the private sector’s first observation at the gate. One flight is a demonstration, not a cadence, and the public sector’s record (PSLV, GSLV, LVM3) remains the country’s launch credential. That credential is itself modest. India flew 56 orbital launches in 2015–2025, an average of about five a year and never more than seven, with four failures (Table 9). PSLV, the workhorse vehicle, then failed on consecutive flights, in May 2025 and January 2026 [Wikipedia, 2026b]. Cadence is the binding gate for the public sector too, and it is the benchmark a private provider will be measured against.

The human spaceflight programme, Gaganyaan (Rs 20,193 crore), targets its first uncrewed flight in the fourth quarter of 2026 and a crewed flight in 2027 [DD India, 2026b].

6.3 Geopolitical reading

Space is where India’s geopolitical position is least contested and its dependence least visible. Since 2022, Russian launch services have been unavailable to Western customers, which narrows their choice of launch provider. That leaves room for a credible non-Chinese, non-Russian second source of small- and medium-lift launch. The NASA–ISRO NISAR mission, launched in July 2025, shows that government-to-government technical collaboration is working. The dependence (s) is in radiation-hardened electronics, some propulsion components and test infrastructure. It is concentrated in allied rather than Chinese supply, so it is exposed to export licensing (for example, U.S. controls on space-grade components) rather than to coercion.

The listing of SpaceX in 2026 illustrates a financial channel that matters for India. Indian listed space-related equities repriced on a foreign comparable with no change in their own fundamentals [HDFC Sky, 2026]. When valuations follow global narratives and qualification is scarce, prices move with the story. That is the condition under which a public ledger of flight milestones would be most valuable.

7 The financing constraint common to all three

All three sectors need patient risk capital to cross their gates, and India supplies that kind of capital least readily. Households place 54 percent of financial savings in deposits and only 13 percent in risk capital. The Employees’ Provident Fund (Rs 24.8 lakh crore) and the National Pension System (Rs 14.4 lakh crore) hold nothing in alternative investment funds, and insurers use less than 1 percent of their permitted headroom [Urbanomics, 2026]. Domestic flows into private markets run at Rs 1.5–2.0 lakh crore a year against Rs 3.0 lakh crore from abroad. Even the largest Indian private-equity managers raise about 85 percent of their funds from foreign investors.

By contrast, liquid public-market capital is abundant. Domestic institutions owned a record 24.9 percent of the Nifty 50 in March 2026, while foreign portfolio investors’ share fell to a 12-quarter low of 22.8 percent [Business Standard, 2026a]. But that capital flows through index and large-cap products, and coverage of the listed long tail is thin. An estimated 78 percent of NSE-listed mid-caps above Rs 500 crore have no analyst coverage [ssr, 2026].

The consequence for strategic sectors is a financing mismatch. The capital that is plentiful is liquid and wants public prices. The risk that needs financing is illiquid and sits at private, pre-qualification gates. Two partial remedies follow from the framework. First, a public ledger of gate outcomes (FDA classifications, scheme milestones, launch records) would let the liquid market price listed suppliers on qualification rather than on narrative. Second, instruments that pay on gates (milestone-linked grants, completion guarantees, sales-linked incentives) shift the illiquid risk to the parties best able to judge π .

8 Watch-list and policy implications

Table 10 lists the dated events. We draw six policy implications.

Table 10: Dated events that will test the argument, September 2026 – 2027

Expected	Event	Sector	What it reveals
Pending	Magnet-scheme award (5 of 20 bidders)	Minerals	Whether selection weights feedstock access (s) or balance sheet (K)
2026	IREL Gudur 10,000 tpa monazite plant commissions	Minerals	Domestic oxide route; any slip is information
Drafting	Private monazite access framework	Minerals	Whether any awardee can build a domestic feedstock chain
10 Nov 2026	China’s wave-2 export-control suspension expires	Minerals	$p(\rho)$ for every import-dependent magnet line
Q4 2026	Gaganyaan first uncrewed flight (G1)	Space	Public-sector human-rating gate
Continuous	FDA inspections, warning letters, import alerts	Pharma	π for Indian sites; whether FY26 enforcement rise persists
Rolling 2026–27	SHANTI Act final rules; first private licence application	Nuclear	Whether private entry converts from statute to project
~Apr 2027	One-year review of Section 232 generic exemption	Pharma	Durability of India’s tariff position
2027	Gaganyaan crewed flight	Space	Human-spaceflight qualification

Notes: Dates as announced; programme dates in India have historically slipped, and the slip is itself an observation.

- P1. Measure qualification, not announcement.** Every scheme should publish a gate ledger: the milestone, the criterion set in advance, the date, and the verdict. An announcement, memorandum or bid count is not a milestone.
- P2. Pay on gates.** Extend the magnet scheme’s sales-linked design to other strategic schemes. Where capital subsidies are unavoidable, release them in tranches against independently verified milestones, with counterparty verification treated as the first gate.
- P3. Treat input dependence as a separate target.** Measure and report s (the China share of critical inputs) for each scheme alongside output. Import substitution at the last stage should not be reported as reduced dependence.
- P4. Resolve monazite together with nuclear.** Settle the monazite-access framework and the SHANTI rules together. They are the same ore, the same radiological licence and the same regulator, and sequencing them apart delays the only domestic feedstock route for the magnet scheme.
- P5. Invest in the pharmaceutical gate directly.** India’s OAI rate has stayed at the non-EU norm while its share of oversight nearly doubled, and has not converged towards the best performers. Shared quality infrastructure, data-integrity tooling and inspection-readiness programmes for mid-sized firms may have a higher return per rupee than more capacity incentives, because the geopolitical premium is paid only on qualified output.
- P6. Open domestic patient capital to gated risk.** Permitting and encouraging pension and insurance allocations to milestone-linked instruments would put India’s largest pools of

long-horizon savings behind its strategic sectors, with the gate structure limiting the risk.

9 Limitations

This is a descriptive policy paper, not a causal evaluation, and several limits bound its claims.

- *Descriptive, not causal.* The pharmaceutical findings describe trends in FDA outcomes. They do not identify the effect of BIOSECURE, tariffs or incentives on qualification, and they could reflect changes in FDA targeting and staffing as well as in Indian plant quality.
- *Selection into inspection.* The FDA chooses which sites to inspect, so the OAI rate is a rate among inspected sites and not a population rate. Table 8 addresses composition and within-site change, but cannot rule out that the FDA targets riskier Indian sites than it targets elsewhere. Shifts towards unannounced or for-cause inspections also change the denominator.
- *Inspection share is not supply share.* India’s growing share of FDA inspections measures where the regulator spends its effort. It is corroborated by India’s rising share of U.S.-bound exports (Table 3), but it is not itself a measure of market share.
- *Reporting lags and partial years.* FY2026 is incomplete, and classifications are posted with a lag, so FY2026 inspection counts will rise. The warning-letter comparison is conservative for that reason.
- *Archive gaps.* Import-alert history is reconstructed from archived captures whose depth varies by alert and includes gaps. Removal dates are known only to the interval between captures, and 2 spells are left-censored.
- *Secondary sources.* Trade, investment and space-sector figures come from secondary sources marked in the bibliography and have not been re-verified against primary documents.
- *Two sectors without a gate series.* For minerals and space we describe gates but cannot yet measure π . The watch-list in §8 is how that measurement begins.

10 Conclusion

India’s strategic-sector policy has so far been judged mainly on inputs: outlays approved, bids received, capital raised. Geopolitics has raised the stakes of that choice of measure. The premium the world will pay for non-Chinese supply is paid only on output that qualifies. India’s exposure to Chinese inputs is incurred on everything, qualified or not. In pharmaceuticals, the one sector where the gate can be measured, India now accounts for the largest share of the FDA’s foreign drug inspections. Its failure rate at that gate has not improved, even at the same plants, and unannounced inspections have made the gate harder. In critical minerals, a well-designed incentive rests on a feedstock that the law does not yet allow the private sector to process. In space, capital has arrived before the flight record that would justify it. None of these is a reason for pessimism. They are reasons to watch and fund the gates, and to publish what happens at each of them.

About Counterfoil

Counterfoil benchmarks India's critical industries (pharmaceuticals, critical minerals and space) and is building a forensic research model that tracks the regulatory, technical and commercial checkpoints that decide whether announced capacity becomes real capability. Its work is built for regulators, policymakers and investors who need to know where India's industrial claims stand. counterfoil.in

References

The mid-cap coverage desert: Analyst coverage and pricing in NSE-listed mid-caps. SSRN Working Paper 6456781, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=6456781, 2026.

AbbVie. AbbVie and Ichnos Glenmark Innovation announce exclusive global licensing agreement for ISB 2001. <https://news.abbvie.com/2025-07-10-AbbVie-and-Ichnos-Glenmark-Innovation-IGI-Announce-Exclusive-Global-Licensing-Agreement-for-ISB-2001,-a-First-in-Class-CD38xBCMAxCD3-Trispecific-Antibody>, July 2025.

Al Jazeera. India, US strike critical minerals deal: What's in it, why does it matter? <https://www.aljazeera.com/economy/2026/5/26/india-us-strike-critical-minerals-deal-whats-in-it-why-does-it-matter>, May 2026.

All India Radio News. India, US agree to expand cooperation under Pax Silica and technology sectors. <https://www.newsonair.gov.in/india-us-agree-to-expand-cooperation-under-pax-silica-and-technology-sectors>, April 2026.

Business Standard. Foxconn pulls out of semiconductor plant JV with Anil Agarwal's Vedanta. https://www.business-standard.com/companies/news/foxconn-pulls-out-of-semiconductor-plant-jv-with-anil-agarwal-s-vedanta-123071000944_1.html, July 2023.

Business Standard. Wall st to SIPs: DII ownership at record high, FIIs slip to 12-quarter low. https://www.business-standard.com/finance/personal-finance/wall-st-to-sips-dii-ownership-at-record-high-fiis-slip-to-12-quarter-low-126050601281_1.html, 2026a. [secondary].

Business Standard. India's spacetechn startups raise \$871 million as private sector takes off. https://www.business-standard.com/companies/start-ups/india-s-spacetechn-startups-raise-871-million-as-private-sector-takes-off-126072801130_1.html, July 2026b. [secondary].

Business Today. Inside the India-US interim trade agreement: Reciprocal tariffs on india to come down to 18%, 0% duty on generic pharma. <https://www.businesstoday.in/latest/economy/story/inside-the-india-us-interim-trade-agreement-reciprocal-tariffs-on-india-to-come-down-to-18-0-duty-on-generic-pharma-515053-2026-02-07>, February 2026. [secondary].

Center for Strategic and International Studies. Rare earth export restrictions one year later. <https://www.csis.org/analysis/rare-earth-export-restrictions-one-year-later>, 2026.

CIRS Group. China temporarily suspends export controls on key raw materials, including rare earths, lithium batteries, and diamonds. <https://www.cirs-group.com/en/chemicals/china-temporarily-suspends-export-controls-on-key-raw-materials-including-rare-earths-lithium-batteries-and-diamond>, November 2025.

Christopher Clayton, Matteo Maggiori, and Jesse Schreger. A framework for geoeconomics. Working Paper 31852, National Bureau of Economic Research, 2023.

Counterfoil. India: Critical industrial capabilities funding, 2026a. Internal research brief, 21 September 2026; compiled from PIB, ISM, ANRF, TDB and Ministry of Mines releases.

Counterfoil. Out-of-sample prediction of FDA escalation for Indian drug sites, 2026b. Internal report, 22 September 2026.

DD India. Government receives 20 bids for rare earth permanent magnet manufacturing scheme. <https://ddindia.co.in/2026/08/government-receives-20-bids-for-rare-earth-permanent-magnet-manufacturing-scheme/>, August 2026a.

DD India. India’s space sector enters new era with private players, bigger missions and global partnerships. <https://ddindia.co.in/2026/09/indias-space-sector-enters-new-era-with-private-players-bigger-missions-and-global-partnerships/>, September 2026b.

Discovery Alert. India private sector thorium access: Monazite policy 2026. <https://discoveryalert.com/india-private-sector-thorium-access-monazite-policy-2026/>, 2026. [secondary].

Down To Earth. India’s battery PLI scheme hit just 2.8% of target in 4 years. <https://www.downtoearth.org.in/energy/indias-battery-pli-scheme-hit-just-28-of-target-in-4-years>, 2026a.

Down To Earth. Union budget 2026 bets on critical minerals, nuclear energy, advanced science. <https://www.downtoearth.org.in/science-technology/union-budget-2026-bets-on-critical-minerals-nuclear-energy-advanced-science>, February 2026b.

Farmonaut. India monazite reserves: Rare earth beach sands by state. <https://farmonaut.com/mining/india-monazite-reserves-rare-earth-beach-sands-by-state>, 2026. [secondary].

Henry Farrell and Abraham L. Newman. Weaponized interdependence: How global economic networks shape state coercion. *International Security*, 44(1):42–79, 2019. doi: 10.1162/isec_a_00351.

FDA Law Blog. WuXi AppTec’s 1260H listing brings the BIOSECURE act back to center stage. <https://www.thefdalawblog.com/2026/06/wuxi-apptecs-1260h-listing-brings-the-bio-secure-act-back-to-center-stage/>, June 2026.

Forbes India. Five times indian space-tech startups made global headlines this year. <https://www.forbesindia.com/photogallery/news/5-times-indian-space-tech-startups-made-global-headlines-this-year/2997948/1>, 2026. [secondary].

Geopolitical Monitor. India’s bid to build the magnets the west needs. <https://www.geopoliticalmonitor.com/indias-bid-to-build-the-magnets-the-west-needs/>, 2026. [secondary].

HDFC Sky. SpaceX listing boosts interest in indian space stocks. <https://hdfcsky.com/news/spacex-listing-boosts-interest-in-indian-space-stocks>, 2026. [secondary].

India Briefing. US 100% tariff on patented pharma products: India’s generic drug exports get a temporary pass. <https://www.india-briefing.com/news/us-patented-pharma-tariff-2026-india-generic-drug-exports-exempted-43899.html/>, 2026. [secondary].

Indian Defence News. India’s space economy surges to \$9 billion, projected to quadruple in next decade. <https://www.indiandefensenews.in/2026/08/indias-space-economy-surges-to-9.html>, August 2026. [secondary]; reports Department of Space and IN-SPACe figures.

Indian Space Research Organisation. Launch missions. <https://www.isro.gov.in/LaunchMissions.html>, 2026.

IndraStra Global. Magnets, minerals, and leverage: India’s rare earth predicament. <https://www.indrastra.com/2025/06/magnets-minerals-and-leverage-indias.html>, June 2025. [secondary]; import figures attributed to The Times of India.

International Energy Agency. Rare earth elements: Executive summary. <https://www.iea.org/reports/rare-earth-elements/executive-summary>, 2025.

Réka Juhász. Temporary protection and technology adoption: Evidence from the Napoleonic blockade. *American Economic Review*, 108(11):3339–3376, 2018. doi: 10.1257/aer.20151730.

Réka Juhász, Nathan Lane, and Dani Rodrik. The new economics of industrial policy. Working Paper 31538, National Bureau of Economic Research, 2023.

Nathan Lane. Manufacturing revolutions: Industrial policy and industrialization in South Korea. SSRN Working Paper 4991735, 2024.

Moneycontrol. Indian pharma sites see fewer USFDA official actions in FY26 even as surprise inspections expand. <https://www.tradingview.com/news/moneycontrol:8f80166ea094b:0-indian-pharma-sites-see-fewer-usfda-official-actions-in-fy26-even-as-surprise-inspections-expand/>, 2026. [secondary].

Observer Research Foundation. India’s rise as global pharmacy masks deep dependence on China. <https://www.orfonline.org/expert-speak/india-s-rise-as-global-pharmacy-masks-deep-dependence-on-china>, December 2025.

Pharmaceuticals Export Promotion Council of India. Pharmexcil handbook. https://pharmexcil.com/uploadfile/Hand_Book_14_06_2025_final.pdf, June 2025. Tables of exports by product group and country, FY2022–23 to FY2024–25.

Prime Minister’s Office, Government of India. Cabinet approves Rs 7,280 crore scheme to promote manufacturing of sintered rare earth permanent magnets (REPM). https://www.pmindia.gov.in/en/news_updates/cabinet-approves-rs-7280-crore-scheme-to-promote-manufacturing-of-sintered-rare-earth-permanent-magnets-repm/, November 2025.

Rare Earth Exchanges. India EV NdFeB magnet supply gap and localization delay. <https://rareearthexchanges.com/news/india-ev-ndfeb-magnet-supply-gap/>, September 2026. [secondary].

Dani Rodrik. Industrial policy for the twenty-first century. SSRN Working Paper 617544, 2004.

Ropes & Gray. BIOSECURE act enacted. <https://www.ropesgray.com/en/insights/alerts/2026/01/biosecure-act-enacted>, January 2026. Signed 18 December 2025 as part of the FY2026 NDAA.

Sidley Austin. U.S. FDA plans to increase the number of surprise foreign inspections. <https://www.sidley.com/en/insights/newsupdates/2025/05/us-fda-plans-to-increase-the-number-of-surprise-foreign-inspections>, May 2025. On FDA’s 6 May 2025 announcement expanding unannounced foreign inspections; the India pilot began in March 2022.

SpaceNews. Skyroot Aerospace reaches orbit on first Vikram-1 launch. <https://spacenews.com/skyroot-aerospace-reaches-orbit-on-first-vikram-1-launch/>, July 2026.

S&R Associates. Nuclear energy act: Transforming india’s nuclear energy landscape. <https://www.snrlaw.in/nuclear-energy-act-transforming-indias-nuclear-energy-landscape/>, 2025.

The Core. Why india’s plan for China-free rare earth magnets leaves raw material gap. <https://www.thecore.in/opinion/the-plinth/india-rare-earth-magnet-scheme-china-oxide-dependence-tender-870897>, 2026. [secondary].

Trading Economics. China lifts curbs on rare earths, fertilizer exports to india. <https://tradingeconomics.com/india/news/news/478768>, August 2025. [secondary]; 19 August 2025.

Urbanomics. Disaggregating india’s savings and its risk capital challenge, September 2026. 18 September 2026; draws on CRISIL, IVCA and 360 ONE, *Unlocking Domestic Capital*.

U.S. Embassy and Consulates in India. United states and india sign strategic critical minerals cooperation framework. <https://in.usembassy.gov/united-states-and-india-sign-strategic-critical-minerals-cooperation-framework/>, May 2026.

U.S. Food and Drug Administration. FDA Data Dashboard: Inspections, classifications, compliance actions and import refusals. <https://datadashboard.fda.gov>, 2026a. Bulk extracts retrieved September 2026; point-in-time snapshots in Counterfoil corpus.

U.S. Food and Drug Administration. Drug establishments current registration site. <https://www.accessdata.fda.gov/scripts/cder/drls/>, 2026b. Indian establishments geocoded to postcode in Counterfoil corpus.

U.S. Food and Drug Administration. Import alert 66-40: Detention without physical examination of drugs from firms which have not met drug GMPs. https://www.accessdata.fda.gov/cms_ia/importalert_189.html, 2026c. Historical states reconstructed from Internet Archive captures, 2009–2026.

U.S. Government Accountability Office. Drug safety: FDA should take additional steps to improve its foreign inspection program. Technical Report GAO-22-103611, GAO, 2022. URL <https://www.gao.gov/products/gao-22-103611>.

U.S. Government Accountability Office. Drug safety: FDA has faced persistent challenges overseeing foreign drug manufacturing. Technical Report GAO-24-107359, GAO, 2024. URL <https://www.gao.gov/products/gao-24-107359>.

U.S. Government Accountability Office. Drug safety: FDA should implement strategies to retain its inspection workforce. Technical Report GAO-25-106775, GAO, 2025. URL <https://www.gao.gov/products/gao-25-106775>.

Wikipedia. IREL (India) Limited. [https://en.wikipedia.org/wiki/IREL_\(India\)](https://en.wikipedia.org/wiki/IREL_(India)), 2026a. [secondary]; plants and mandate.

Wikipedia. List of PSLV, GSLV and LVM3 launches; small satellite launch vehicle. https://en.wikipedia.org/wiki/List_of_PSLV_launches, 2026b. [secondary]; retrieved 23 September 2026; GSLV series rebuilt flight by flight because the page’s summary chart is misaligned.

World Nuclear Association. Nuclear power in india. <https://world-nuclear.org/information-library/country-profiles/countries-g-n/india>, 2026.

A Data appendix

Corpus. All FDA-derived exhibits are computed from Counterfoil’s point-in-time store of FDA records. Each record carries its source URL, the time it was retrieved and a cryptographic hash of the source document, and no record is overwritten after capture. The store covers four sources: inspection classifications for all countries, compliance actions (warning letters and injunctions), the history of Import Alert 66-40 listings and removals reconstructed from archived captures, and the current register of Indian drug establishments with geocodes.

Definitions. *Drug inspections* are records with product type “Drugs.” Country groups use the FDA country code, with China meaning mainland China; records without a country code are excluded from the rest-of-world group. *Warning letters* are compliance actions of type “Warning Letter” with product type “Drugs.” An *Indian 66-40 listing* is a transition record whose firm address

ends in an Indian country designation. State assignment of establishments uses the geocoder's matched address, falling back to the registered address.