Ch. 4

"License-Out": How Chinese Pharmaceutical Companies Sustained Innovation under Cost Containment Reform

Victoria Liu*

Abstract

How can firms sustain a transition toward innovation when reform weakens the old model before institutions supporting the new one are fully usable? China's pharmaceutical innovation boom presents this puzzle. Regulatory reforms made novel-drug development increasingly feasible, but domestic institutions for financing and commercializing innovation remained incomplete. Meanwhile, National Volume-Based Procurement placed firms under severe financial pressure by weakening the established generic model. Yet drug-development activity accelerated.

I argue that firms can bridge such a reform-induced support gap by activating latent institutional alternatives: institutions outside the reforming system that already supply needed support but were previously peripheral. For Chinese pharmaceutical firms, the global market for cross-border licensing offered a way to monetize promising drug candidates before they generated reliable domestic returns. By licensing overseas rights while retaining their domestic pipelines, firms could use international transactions to sustain development at home.

I evaluate the argument using firm-level pharmaceutical sales, quarterly drug-registration records, and licensing transactions. Compared with firms facing no NVBP exposure, firms facing the average exposure among those affected were estimated to record 9.8 additional weighted registrations per 100 firms annually after 2019, equivalent to 26.4% of the pre-NVBP mean. Among firms with similar prior development histories and reform exposure, those completing their first license-out subsequently recorded an estimated 10.2 additional domestic Phase I–III registrations over twelve quarters relative to matched firms, with no comparable increase in bioequivalence registrations. A case study of Jiangsu Hengrui Pharma traces this process within a major

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incumbent whose innovative transition had initially depended on profits from its older business model.

The findings distinguish the pressure that prompts organizational change from the support that sustains it. Reform may weaken an established model before its replacement can support firms making the transition. During this interval, an institution outside the reforming system can provide a temporary bridge, although only firms with the capabilities needed to access it can benefit.

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4.1 Introduction

China has rapidly emerged as a major source of pharmaceutical innovation. Between 2019 and 2023, the annual number of accepted novel-drug investigational new drug applications rose from 688 to 2,298, while new drug applications increased from 30 to 133 (Tan et al. 2025). By 2024, China accounted for approximately 18% of first global launches of new molecular entities, placing it second worldwide (Clarivate 2025). At the end of 2025, Chinese firms originated 4,751 active novel drug candidates, or 33.7% of the global pipeline (Pharmcube 2026).

What makes this rise especially puzzling is its timing. Pharmaceutical innovation rests on institutions that make both invention and commercialization possible. Firms must finance years of uncertain research, establish the safety and efficacy of their products, and secure market access after approval (Arrow 1978; Freeman 1987; Nelson 1993; Pavitt 1995; Hall and Lerner 2009). Their willingness to make these investments depends heavily on whether they can expect adequate future returns (Acemoglu and Linn 2003; Giaccotto, Santerre, and Vernon 2005; Brown and Petersen 2011; Howell 2017). Beginning in 2015, China strengthened one part of this institutional architecture by reforming drug review and aligning its technical standards more closely with international practice. These changes made novel-drug development increasingly feasible, yet the institutions needed to convert successful development into reliable commercial returns lagged behind. Firms seeking public reimbursement faced steep price concessions and delays in coverage, while inclusion on the reimbursement list did not guarantee timely access to hospitals (National Healthcare Security Administration 2019; H. Zhu et al. 2022; Wang et al. 2025).

The timing is more surprising still because China's innovation boom coincided with an aggressive campaign of pharmaceutical cost containment. Starting in 2019, the National Volume-Based Procurement program (NVBP) pooled demand from public medical institutions and allocated large purchasing volumes through centralized bidding. In the first round, winning prices fell by an average of 52%, with the largest reduction reaching 96% relative to the lowest 2017 purchase prices in the pilot cities (Joint Procurement Office 2018; National Healthcare Security Administration 2018b; Z. Zhu et al. 2023).

NVBP did not directly regulate novel drug prices, but it placed Chinese pharmaceutical firms under severe financial pressure just as they were trying to innovate. Yet innovation accelerated rather than stalled, even though the domestic institutions supporting the new model remained incomplete. How did firms sustain this transition while reform was weakening the old model before the new one was ready?

This puzzle speaks to a broader problem of institutional change. Research has extensively examined how institutions make investment and industrial upgrading possible (North and Weingast 1989; Weingast 1993; Olson 1993; Acemoglu, Johnson, and Robinson 2001). Yet institutions do not become fully usable as soon as formal reforms are announced. Administrative capacity and settled expectations often develop more slowly (North 2013; Roland 2004; Besley et al. 2022; Williams 2021). Reform thus creates an interval in which established support has been removed but its intended replacement remains incomplete. The previous chapter showed how such an interval generated organizational strain in China's public hospitals. This chapter asks why pharmaceutical firms facing a comparable problem were nonetheless able to continue upgrading.

I argue that some firms bridged this *reform-induced support gap* by activating a latent institutional alternative: the global market for cross-border drug licensing. This market already connected developers of promising candidates with foreign companies able to finance further development and commercialize drugs abroad (Teece 2008; Arora, Fosfuri, and Gambardella 2001; Gans and Stern 2002). Regulatory alignment made Chinese drug candidates and clinical evidence easier for foreign partners to evaluate, and NVBP increased firms' need to use the channel. License-out agreements allowed Chinese firms to obtain current payments and overseas development support without giving up their domestic pipelines. Because pharmaceutical rights could be divided territorially, firms could license foreign rights while retaining Greater China rights and continuing research at home.

I evaluate this argument using firm-level pharmaceutical sales, quarterly registrations with China's Center for Drug Evaluation, and cross-border licensing transactions. Moving from zero exposure to 44.8%, the mean among exposed firms, is associated with about 9.8 additional weighted registrations per 100 firms annually after 2019, equivalent to 26.4% of the pre-NVBP mean and consistent with the prediction that firms under greater reform pressure reoriented more strongly. Among firms pursuing novel-drug development, I compare firms completing their first license-out with firms that had similar prior development histories and reform exposure. Across the twelve quarters following a first license-out, license-out firms recorded an estimated 10.2 additional domestic Phase I–III registrations relative to matched firms, with no comparable increase in bioequivalence registrations. A case study of Jiangsu Hengrui Pharma traces how foreign licensing helped an established manufacturer preserve its domestic research program after NVBP destabilized the generic profits that had previously financed it.

This chapter makes three contributions. First, it advances research on institutional transition by directing attention to the interval between dismantling an established arrangement and constructing a usable replacement. Reform outcomes depend not only on the relative quality of the old and

new institutions, but also on what actors can rely on while the transition remains incomplete (North 2013; Pierson 2000; Crouch and Farrell 2004). The comparison with public hospitals shows that access to such support depends partly on whether actors possess assets that can be valued outside the domestic system. Second, the chapter broadens accounts of the developmental state. States can promote industrial upgrading by constructing domestic institutions, but they can also build interfaces through which firms reach institutions operating elsewhere (Mazzucato 2018; Aiginger and Rodrik 2020; Bulfone 2023; Juhász and Lane 2024). China's regulatory upgrading made domestic pharmaceutical assets more internationally legible without reproducing the global licensing market at home. Third, the chapter contributes to global political economy by showing that global markets can temporarily perform functions missing from an incomplete domestic system. Existing research demonstrates how foreign investors, buyers, and certification regimes help firms overcome domestic constraints (Hail and Leuz 2009; Atkin, Khandelwal, and Osman 2017; Fiankor et al. 2020). This chapter explains why domestic reform can make those previously peripheral institutions newly important to an industrial transition. Their value as a bridge, however, remains contingent on continued market access and political permission (Farrell and Newman 2019; Caldara et al. 2020; Benguria et al. 2022).

The chapter proceeds as follows. The next section reviews research on the institutional foundations of innovation and the transitional problems created when reform outpaces institutional construction. I then develop the concepts of reform-induced support gaps and latent institutional alternatives. The following section describes China's transition from generic commercialization toward a price-disciplined and globally connected innovation model. I next present the firm-level data, empirical strategy, and results. A case study of Jiangsu Hengrui Pharma traces the proposed mechanism. The final section considers what the divergence between hospitals and pharmaceutical firms implies for China's innovation model and for the broader relationship between institutional discipline and replacement.

4.2 Literature Review

4.2.1 Innovation as an Institutional Achievement

The political economy literature has long argued that credible institutions make sustained investment possible. Firms are more willing to commit resources when they can expect their property rights to remain secure, contracts to be enforced, and political authorities to refrain from expropriating their investments (e.g., North and Weingast 1989; Weingast 1993; Olson 1993; Acemoglu,

Johnson, and Robinson 2001).

Innovation represents a particularly challenging version of this commitment problem. Compared with investments in established production, innovative activities require firms to incur substantial sunk costs before they know whether their projects are technologically feasible or commercially valuable. The returns to such investments are unusually uncertain, making research and development especially vulnerable to financing and appropriability problems (e.g., Arrow 1978; Bronwyn 2010; William 2015).

Thus, beyond general institutional protections, innovation also depends on a specialized set of institutions that finance early-stage risk, supply skilled labor, evaluate and certify novel products, protect intellectual property, and provide credible pathways from invention to market (e.g., Freeman 1987; Pavitt 1995; Nelson 1993). Innovation is therefore not simply the achievement of isolated firms, but the product of broader institutional systems. States around the world play an active role in creating and maintaining the institutions needed to sustain risky innovative activity (e.g., Mazzucato 2018; Aiginger and Rodrik 2020; Bulfone 2023).

4.2.2 When Reform Outpaces Institutions

4.2.2.1 From Enactment to Operation

As institutions are key to innovation, institutional upgrading poses a practical problem for both states and firms. Building a usable innovation system takes time. While governments can enact formal rules in discrete moments, they cannot make the resulting institutional system operational at the same speed. It is insufficient to formally pass a law, set up an agency, or announce a new funding program. The new rule must be staffed, interpreted, funded, routinized, and made credible to the actors expected to rely on it. Formal enactment is therefore only the beginning rather than the end of institutional upgrading.

The first source of delay is organizational capacity. New institutions become consequential only when public organizations can make use of them. Agencies require budgets, trained personnel, information systems, evaluative criteria, and routines for monitoring and enforcement. These capabilities cannot be legislated into existence. It is well documented that policy performance varies substantially with the personnel and organizations responsible for implementation (e.g., Besley et al. 2022; Best, Hjort, and Szakonyi 2023; Williams 2021). Ambitious industrial and innovation programs are particularly prone to failure when governments lack the administrative capacity to carry them out (e.g., Juhász and Lane 2024; McLaren and Kattel 2025). States may therefore

authorize a new regulatory or funding regime well before the responsible organizations can administer it consistently. This gap need not reflect a lack of political commitment. It can arise because organizational capacity accumulates more slowly than formal authority.

A second source of delay stems from institutional complementarity. Innovation depends not on a single rule or organization but on a system of interdependent supports: Intellectual-property (IP) institutions must allocate claims while preserving disclosure and opportunities for follow-on invention (e.g., Sampat and Williams 2019; Hegde, Herkenhoff, and Zhu 2023); financial institutions and public funding opportunities must help absorb early-stage risks and support commercialization (e.g., Lerner and Nanda 2020; Smith 2020); regulatory agencies must evaluate and certify unfamiliar products (e.g., Berger, Chandra, and Garthwaite 2021); and educational and labor-market institutions must train specialized talent (e.g., Laursen et al. 2020). These institutions are not merely additive. IP protection is of limited value when firms cannot finance their development. Public funding and education may produce few marketable products when commercialization channels are missing. Weakness in one component can therefore stall progress elsewhere (e.g., Mohnen and Röller 2005; Cirera et al. 2020). Because states must build and coordinate a web of complementary institutions rather than a single organization, the pace of institutional upgrading is constrained by its slowest component.

A third source of delay is credibility. Even a formally complete and adequately resourced institution may not immediately provide a credible basis for costly investment. Formal rules can change quickly, whereas routines, informal norms, and shared expectations often change more slowly (e.g., North 2013; Roland 2004). Firms need time to learn how agencies interpret new rules in practice, whether enforcement is consistent, whether promised support will survive political or economic stress, and whether investors and other firms will organize their own behavior around the same arrangements. Scholars have shown that firms respond to institutions as they perceive and experience them, not solely as they are written (e.g., Weng et al. 2021; Cukierman, Web, and Neyapti 1992; Romelli 2022). Institutional upgrading is partly a coordination problem, where the uptake of new institutions increases as actors expect others to rely on them as well. Credibility cannot be manufactured by decree. It accumulates through repeated decisions, which necessitates time (e.g., Levi 2019, 2011).

These sources of delay are cumulative rather than independent. Uneven implementation and missing complements delay the very experiences through which actors learn whether a new regime is reliable. Together, they create an interval in which reform exists in writing but does not yet constitute a fully usable support system. The next subsection shows why this interval becomes

more consequential when institutional reform also erodes arrangements on which firms previously relied.

4.2.2.2 Reform-Induced Support Gap

The delays described above do not necessarily create a support gap. If institutional upgrading is purely additive, firms may continue operating under existing arrangements while waiting for new institutions to mature. The problem becomes sharper when reform is subtractive as well as additive. Reform often changes the relative viability of economic activities rather than simply expanding the institutional options available to firms. By tightening rules, withdrawing rents, or making previously tolerated practices newly risky, reform can weaken the arrangements on which firms currently rely before new supports become operational. What would otherwise be a period of institutional waiting thus becomes a support gap.

It is important to acknowledge that prior arrangements need not be efficient or normatively desirable to matter. Institutions persist partly because actors organize their expectations and investments around rules and relationships that they expect others to observe (e.g., North 2013; Aoki 2001; Greif 2006; Helmke and Levitsky 2004). Once routinized, such arrangements can provide functional stability even while undermining overall welfare.

Comparative research illustrates this ambivalence. Rent-based exchanges, political brokerage, and even selective enforcement can stabilize exchange and mediate access to markets or public resources, even when these arrangements are inefficient, unfair, or legally ambiguous (e.g., Holland 2016; Auerbach 2019; Gallien 2020). In China, corruption in the form of access money facilitated investment despite generating severe distortions (Ang 2020).[1] While these preexisting arrangements are certainly not desirable, they may contain established systems of exchange and coordination on which actors have learned to rely.

For firms, established arrangements may provide predictable revenue or market access without supporting innovation itself. Indeed, they may anchor firms in a rent-based and less-innovation-intensive equilibrium. Yet the revenue slack can still sustain firm survival and help finance costly innovation reorientation, especially because R&D is sensitive to internal liquidity and financing constraints (e.g., Brown and Petersen 2011; Howell 2017). Reform can therefore strengthen firms' incentives and long-term capacity to innovate while weakening their immediate capacity to do so.

1. Chapter 3 develops this argument in greater detail in the context of China's public health sector, showing how corrupt and discretionary arrangements could supply organizations with informal fiscal and coordination capacities in spite of social costs.

Compressing the old arrangements removes not only the distortions but also some of the resources and predictability around which firms had organized their operations (Autor et al. 2019).

The pain of transition is not unique to innovation. Research on post-socialist countries show how reforms disrupted established production relationships before market institutions could replace them, leading to substantial transitional output losses (e.g., Blanchard 1996; Roland and Verdier 1999; Campos and Coricelli 2002). Similarly, India's demonetization attempt withdrew the established means of exchange faster than its replacement could circulate, causing sharper contractions where cash shortages were more severe (Chodorow-Reich et al. 2020). Despite different settings and purposes, these cases illustrate the same temporal problem with reform. Even reforms that promise substantial long-run gains can impose severe short-run costs when existing supports are withdrawn before their replacements become usable.

In short, innovation requires strong institutions, and states may genuinely seek to build them. Yet these institutions take time to mature, while the act of reform may dismantle existing supports before their replacements are ready. The resulting reform-induced gap imposes short-term costs even when reform promises long-term gains. What, if anything, enables firms to sustain a transition toward innovation during this gap?

4.3 Theory

The previous section identified a reform-induced support gap: reform may weaken the arrangements on which firms have relied before the new institutions meant to support innovation have become fully usable. This section develops a theory of how some firms could bridge that interval. The central claim is that reform may revalue institutions it neither creates nor directly targets. Previously marginal alternatives can then become sources of externalized support, providing financing, validation, and market access that remain insufficient within the domestic system.

4.3.1 Latent Institutional Alternatives

The previous section has distinguished between established institutions that reform weakens and new institutions intended to replace them. However, firms rarely face only these two options. Preexisting alternatives may also exist in other markets, jurisdictions, or parts of the value chain. I call these *latent institutional alternatives* — institutions that are already available and capable of supporting a firm's activities but remain peripheral to its strategy under previous conditions. Firms may have made little use of these alternatives because established arrangements offered higher

returns, while sunk investments and familiar routines further raised the cost of switching (e.g., North 2013; Pierson 2000).

That calculus changes when the state actively pursues institutional upgrading which often includes cracking down on institutions that supported the old model. The latent alternative needs not improve, nor must reformers intend firms to use it. Rather, reform changes the alternative's relative appeal. As the expected return to remaining with the established arrangement falls, while the returns to adapting to its intended replacement remain uncertain, previously peripheral alternatives become more attractive. This logic is consistent with how changes in the surrounding environment can undermine the viability of an existing institutional equilibrium (Greif and Laitin 2004) and lead actors to draw upon underused institutional alternatives (Crouch and Farrell 2004). What changes is not necessarily the alternative itself, but the firm's incentive to use it.

Latent institutional alternatives can take several forms. Firms that normally rely on bank credit may turn to trade credit, fintech, or private lenders when formal financing tightens (e.g., Allen, Qian, and Xie 2019; Erel and Liebersohn 2022). Firms dependent on domestic investors or buyers may cross-list abroad, obtain international certification, or enter foreign markets when the domestic market is weak (e.g., Hail and Leuz 2009; Atkin, Khandelwal, and Osman 2017; Fiankor et al. 2020). Innovators that ordinarily commercialize assets themselves may instead license them to external partners, earning upfront payments, milestones, and royalties instead (e.g., Teece 2008; Arora, Fosfuri, and Gambardella 2001).

It is important to note that these alternatives are not inherently superior. They have remained latent because firms had dominant channels which offered relatively higher returns. However, the claim is that these alternatives become particularly salient during a transition when institutional upgrading weakens a profitable established arrangement before its replacement becomes dependable.

4.3.2 Bridging the Gap

Activating a latent institutional alternative can help a firm bridge the reform-induced gap. Rather than depend exclusively on either a weakened established arrangement or its still-maturing replacement, the firm can obtain missing support from another institution already capable of providing it.

This is especially consequential for innovation, where firms must continue to finance uncertain projects long before they generate returns (e.g., Hall and Lerner 2009; Lerner and Nanda 2020). Outside investments, buyers, or licensing partners can keep projects alive before the intended domestic institutions can reliably do so (e.g., Teece 2008; Arora, Fosfuri, and Gambardella 2001;

Gans and Stern 2002). While these alternatives do not guarantee to restore everything firms have lost from the established model, they make continued investment feasible while the transition remains incomplete. Two properties discussed below make them particularly useful.

Institutional Readiness A latent alternative is already operating even if firms have little experience using it. For example, an established overseas capital market would already have its disclosure rules, auditors, analysts, and enforcement mechanisms to provide the information and monitoring needed to make novel assets evaluable and transferable (e.g., Leuz and Wysocki 2016; Roychowdhury, Shroff, and Verdi 2019; Kim and Valentine 2023; Moreira, Klueter, and Asija 2023). Firms are therefore entering a system with an established record of operation, rather than one being constructed around them.

This readiness alleviates three problems associated with institutional upgrading. First, it reduces waiting. Rather than wait for the reforming state to build institutional capacity, train personnel, and commit resources, firms can draw on a system already capable of performing the relevant functions. Second, it alleviates the complementarity problem. Innovation depends on coordinated systems of investors, evaluators, intermediaries, and more, so constructing any single component is insufficient (e.g., Jacobides, Cennamo, and Gawer 2018; Granstrand and Holgersson 2020; Jacobides, Cennamo, and Gawer 2024; Baldwin et al. 2024). A latent alternative provides these complements as an existing ecosystem. Although that ecosystem may be imperfect, firms need not wait for each component to develop domestically. Third, readiness strengthens credibility. Because the alternative has already processed transactions and produced decisions, firms can observe how its rules are applied and form expectations about its operation. Political separation, discussed below, reinforces this advantage by making the support less dependent on the trajectory of the domestic reform.

It is important to clarify that readiness does not make activation costless. Because the alternative was previously peripheral, firms may still need to acquire expertise, satisfy unfamiliar requirements, and establish relationships with new intermediaries (e.g., Kostova et al. 2020; Donnelly et al. 2024). The difference is that they learn against an operating institutional system. Under a still-maturing domestic replacement, firms must adapt while regulators and rules are themselves developing (e.g., Alaassar, Mention, and Aas 2020; Fahy 2022; Kattel, Drechsler, and Karo 2022). Activating a ready alternative therefore narrows a joint problem of institutional construction and firm adaptation into one primarily of firm adaptation.

Political Separation Some latent alternatives offer an additional advantage that their operation is not tied to the implementation of the focal reform. Institutional readiness reduces uncertainty about when support will become available, whereas political separation reduces uncertainty about whether that support will remain available if the reform stalls or changes direction.

Since reform is still in progress, firms may rightfully doubt whether the reform is pursued sincerely, whether responsible agencies will acquire sufficient capacity, or whether the coalition supporting the reform will endure. As enactment often does not settle the political conflict surrounding reform, policies may subsequently be weakened, redirected, or undermined during implementation (e.g., Patashnik 2014; Jacobs and Weaver 2015; Jordan and Moore 2022). These doubts can hold back investments, particularly when commitments are costly to reverse (e.g., Rodrik 1991; Gulen and Ion 2016; Hassan et al. 2019). The reform-induced gap is therefore not only a matter of waiting for institutions to develop. It also exposes firms to uncertainty about whether the institutions will develop at all after patient waiting.

States can sometimes manage this political uncertainty through transitional arrangements of their own (e.g., Lau, Qian, and Roland 2000; Pahle et al. 2018) or by insulating particular commitments by delegating them to a relatively autonomous authority (e.g., Keefer and Stasavage 2003; Dietsch 2020).[2] While these arrangements could be effective, their limitation is that a state-designed bridge would most likely draw on the same agencies, fiscal resources, and political sponsors as the intended reform replacement. If political priorities shift, the bridge and the replacement may weaken together.

Of course, an institution outside the reform's domain still carries risks of its own. Foreign markets fluctuate and cross-border exchanges can become geopolitically contentious (e.g., Caldara et al. 2020; Benguria et al. 2022). The advantage of political separation is not to say that latent alternatives carry lower risk in general, but lower risk associated with the ongoing reform. Since the outside institution remains exposed to a sufficiently different set of political contingencies, if the domestic reform falters, the alternative institution could still continue to operate. Firms can thereby diversify reform-specific risk rather than place both their interim support and their expected returns on the same institutional trajectory. An example of this risk diversification is how firms diversified across foreign markets to be more insulated from country-specific policy uncertainty (e.g., Benguria et al. 2022; Puhr and Müllner 2022).

Reform-induced gaps therefore need not leave firms choosing only between a weakened estab-

2. The credibility of such delegation also depends on the surrounding political constraints.

lished arrangement and an incomplete replacement. Reform can instead prompt them to activate latent alternatives, which has two distinct advantages. Institutional readiness gives firms access to an operating system without waiting for its capacity and complements to be constructed. Political separation makes the continued availability of that system less contingent on the fate of the domestic reform. Together, they can keep adjustment feasible before the intended replacement becomes fully usable and credible. That said, such bridging is neither automatic nor universal. The following section discusses the conditions and boundaries of the argument.

4.3.3 Scope Conditions

4.3.3.1 Who Can Activate Latent Alternatives?

The existence of a ready alternative does not make it equally accessible. Alternative institutions apply their own criteria rather than compensating firms for losses caused by domestic reform. Firms must therefore establish a fit with those criteria. They may do so through recognizable evidence and certifications (e.g., Hsu and Ziedonis 2013; Potoski and Prakash 2009; Javorcik and Sawada 2018; Zuckerman 1999; Kölbel and Busch 2021) or through prior relationships and credible intermediaries (e.g., Diamond 1989; Stuart, Hoang, and Hybels 1999; Podolny 1993; Leblang 2010; Burchardi, Chaney, and Hassan 2019; Armanios et al. 2017). Reform-induced pressure may therefore be widespread even when the capacity to activate an alternative is not.

Gaining access can also be costly. Firms may need to alter their accounting practices, secure IP protection, produce additional evidence, recruit specialized personnel, or cultivate new relationships before the alternative becomes usable. An example of this is how fixed entry costs select which firms can reach foreign markets based on their financing, knowledge, and organizational capacities (e.g., Melitz 2003; Verhoogen 2024). Firms that already possess the relevant resources, or can acquire them quickly, will activate latent alternatives earlier and more successfully than equally pressured firms that cannot. Pressure creates an incentive to look outward, but it does not by itself supply the capacity to do so.

This selectivity also clarifies that the theory is primarily concerned with how firms sustain an emerging transition during institutional change, not the origins of innovation in general. Latent alternatives need not create firms' technological capabilities or initially make innovation attractive. Their distinctive contribution arises once reform has strengthened the incentive to pursue a new model while weakening the resources supplied by the old one. Access to these alternatives can then preserve firms' momentum until support for the new model becomes more secure.

4.3.3.2 When Do States Permit Their Use?

Firm-level capacity is insufficient if the reforming state closes the channel to the alternative. Cross-listings, licensing agreements, partnerships, technology transfers, and other cross-border transactions remain subject to domestic rules governing what may leave the country and on what terms (Quinn 1997; Edison and Warnock 2008). The state need not construct or endorse the bridge as a response to the reform-induced gap. It only needs to refrain from blocking firms from activating these latent alternatives.

Such permission does not need to be explicit. It may take the form of tacit tolerance, regulatory ambiguity, or uneven enforcement. Research on adaptive informal institutions shows how actors can establish durable practices around workarounds to restrictive formal rules (e.g., Tsai 2006; Holland 2016). An example of this is China's variable-interest-entity (VIE) structure which provides firms in restricted sectors with regulatory ambiguity to reach foreign investors and equity markets without the state formally legalizing the underlying arrangement (Chen 2021).

A channel may remain open precisely because it lies outside the focal reform and initially attracts little political attention. But tolerance is not commitment. If the channel grows more salient or becomes associated with capital flight, data security, or strategic technology transfer, the state may restrict or close it (Farrell and Newman 2019).

4.3.3.3 Bridge or Exit?

An activated latent alternative buys time. It does not eliminate the need for the intended institutional upgrading. The outside institution only temporarily performs functions that the domestic system cannot yet provide, allowing firms to continue investing during the transition. The bridging support is functionally substitutive but temporally provisional.

This means that a firm may obtain financing abroad, license an asset to a foreign partner, or seek validation from an external regulator, but it will continue to develop assets, employ personnel, or maintain production at home. By contrast, the same outward turn becomes exit when the firm relocates or withdraws domestic investment. The distinction is not where a transaction occurs, but what that transaction enables the firm to continue doing. Firms use external support to strengthen their position rather than abandon their domestic base (Luo and Tung 2007).

For turning outward to remain a bridge, firms must have some reason to preserve their domestic position. One source is forward-looking: firms may expect the reform's intended replacement even-

tually to become usable and valuable, which depends on the credibility of the reforming authority's commitment to complete and maintain the new arrangement (e.g., Gazmararian and Tingley 2023; Arent and Arndt 2017). A second source is more backward-looking. Firms with sunk investments, specialized workforces, supplier relationships, regulatory standing, or continuing advantages in research and production may remain domestically engaged even under temporarily unfavorable conditions (Dixit 1989). Expectations of future institutional improvement and the value of existing domestic positions may reinforce one another.

Where neither source is strong, access to outside institutions is more likely to turn into exit. Research on "escape" internationalization describes firms moving activity abroad to avoid persistent home-country institutional constraints rather than remaining engaged until those constraints are resolved (Cuervo-Cazurra and Ramamurti 2017).

4.3.4 Testable Implications

How can firms sustain a transition toward innovation when reform weakens the arrangements supporting the old model before institutions supporting the new one are fully usable? I argue that reform can increase the value of preexisting but underused institutional alternatives. Firms able to activate these alternatives can obtain institutional support still missing from the reforming system, allowing them to bridge the reform-induced support gap and maintain innovative momentum. The argument yields two firm-level implications: one concerns what prompts firms to reorient, and the other what enables them to sustain that reorientation.

Reorientation under Asymmetric Pressure When reform weakens the old model in a setting where a viable latent alternative can support the emerging model, firms more exposed to the weakened arrangements should reorient more strongly toward innovation. Because these firms lose more from remaining on the established path, they have stronger incentives to pursue an alternative even while the intended domestic institutional system remains incomplete. Less-exposed firms, whose existing model remains more viable, face less pressure to change and should reorient more slowly.

This implication concerns firms' attempts to transition, not whether those attempts ultimately succeed. The argument would be weakened if greater exposure produced only contraction or exit rather than a reallocation toward innovation, or if more- and less-exposed firms followed similar trajectories. Evidence of greater reorientation among more-exposed firms would show that reform pressure induced a pivot toward innovation. It would not, by itself, establish that alternative institutional support enabled firms to sustain that pivot.

Sustaining the Transition through Alternative Support Second, among firms facing comparable reform pressure and attempting to reorient, those able to activate a latent institutional alternative should be better able to sustain and advance their transition toward innovation. The activated alternative helps firms continue investing despite the reform-induced support gap. Firms that obtain such support should therefore maintain more innovative activity and make greater progress than comparable firms that do not.

Activation is necessarily selective. Preexisting assets, technical capabilities, and records of innovative investment can make firms more legible and credible to alternative institutions. These capabilities may therefore explain both access to alternative support and subsequent innovation. Selective access is consistent with the theory, but it does not by itself demonstrate that the alternative sustained the transition. The bridging claim requires firms that activate alternative support to sustain more innovation than comparable firms with similar prior capabilities and trajectories. The argument would be weakened if activation provided no such advantage, or if it primarily facilitated asset liquidation and withdrawal from domestic innovation. Such patterns would suggest that the alternative merely rewarded prior success or enabled exit rather than bridging the reform-induced support gap.

4.4 Background: China's Pharmaceutical Sector in Transition

China has emerged as one of the world's largest centers of pharmaceutical innovation. In 2024, China was the site of 18% of global first launches of new molecular entities[3], making it the world's second-largest market for new drug launches (Clarivate 2025). By the end of 2025, 4,751 active novel drug candidates originated with Chinese firms, representing 33.7% of the global pipeline. For reference, the United States had 4,019 candidates, representing 28.5% of global launches (see Fig 4.1, Pharmcube 2026). By this measure, China had overtaken the United States as the world's largest source of active novel drug candidates.[4] The scale of China's novel drug pipeline marks a striking departure from the country's earlier trajectory of generic production and domestic commercialization.

What makes China's achievement particularly striking is its timing. China began upgrading the institutional foundations for novel drug development in 2015, through reforms that accelerated drug review and brought its regulatory standards into closer alignment with established interna-

3. Drugs built around active ingredients not previously approved.

4. This count measures pipeline scale, which primarily captures early-stage development in China, and should not be conflated with demonstrated clinical or commercial success. Of the Chinese-origin candidates, 76% remained before Phase II trials.

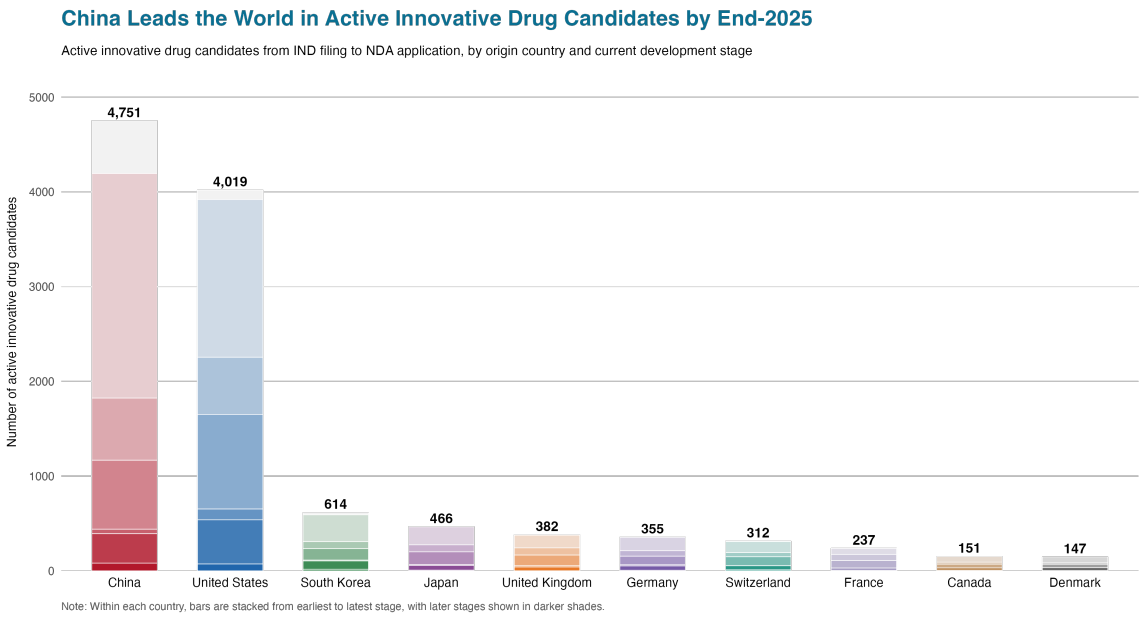


Figure 4.1: Active novel drug candidates by country of origin and development stage, end-2025. *Notes*: The figure presents the ten countries with the largest active pipelines. Candidates are included from investigational new drug filing through new drug application submission. Country is assigned according to the location of the originating organization. Within each country, candidates are ordered from earlier to later development stages, with later stages shown in darker shades. *Source*: Author's visualization based on PharmaCube data (Pharmcube 2026).

tional markets (State Council of the People's Republic of China 2015; International Council for Harmonisation 2017). Yet by late 2018, while these new institutions were still taking shape, the state moved decisively against the commercial model which much of the pharmaceutical industry still depended on. National Volume-Based Procurement subjected generic drugs to centralized price competition, reducing winning prices by an average of 52%, with a maximum reduction of 96% (National Healthcare Security Administration 2018c; Z. Zhu et al. 2023). Cost containment also extended to the emerging market for novel drugs, where drugs admitted through the 2019 National Reimbursement Drug List negotiation accepted an average price reduction of 60.7% in exchange for access to the publicly insured market (National Healthcare Security Administration 2019).[5]

Despite this intense price pressure and the still-maturing domestic institutions for rewarding novel drugs, innovation accelerated rather than stalled. This pattern seems to run against the conventional expectation that R&D is associated with stronger prospective market returns (e.g., Acemoglu and Linn 2003; Giaccotto, Santerre, and Vernon 2005). Between 2019 and 2023, the annual number of accepted novel-drug IND applications increased from 688 to 2,298, while novel-drug NDA applications rose from 30 to 133.[6] The number of innovative-drug varieties approved each year also quadrupled, from 10 to 40 (Tan et al. 2025). China's innovative pipeline not only survived the onset of stringent cost containment, but innovative activities across multiple stages of drug development also increased roughly three- to fourfold during its first five years.

The experience of China's pharmaceutical industry highlights the timing mismatch discussed previously. China was able to transition toward innovation while weakening firms' current sources of revenue faster than the emerging system could reliably finance and reward the pipeline intended to replace them. The central puzzle is not simply why Chinese firms began to innovate. It is how they sustained that transition through the interval between immediate price compression and the delayed and uncertain rewards of successful innovation.

5. Generic drugs are drugs that reproduce an approved reference drug and must demonstrate equivalence in active ingredient, strength, and bioavailability. Novel drugs are based on a new active molecule or biological entity and therefore require original preclinical and clinical evidence.

6. An investigational new drug (IND) application seeks regulatory authorization to begin testing a drug candidate in humans and marks entry into clinical development. A new drug application (NDA) seeks authorization to market a drug after the sponsor has assembled the required preclinical, clinical, and manufacturing evidence. "Accepted" applications have been accepted by the regulator for review but have not necessarily been approved. Application counts may not correspond one-to-one with distinct drug candidates, since one candidate may submit applications for multiple indications or formulations.

4.4.1 The Old Equilibrium: Generics and Commercial Access

Before its innovation boom, China's pharmaceutical sector focused on generic production with access-centered commercialization (Mossialos and Ge 2016). Most firms produced generic or incrementally modified drugs for sale in the domestic market. Because these products were often closely substitutable and quality standards remained unevenly enforced, firms found it difficult to differentiate themselves through product quality or therapeutic value (Ni et al. 2017).

In this crowded and weakly differentiated market, competition instead centered on securing prescriptions. Prescription medicines in China were dispensed predominantly through hospitals, placing local authorities, hospitals, and physicians in unusually powerful positions (e.g., Sun et al. 2008; Lee and Burns 2017). Regulatory approval was only the first step toward commercial success. A drug also needed to qualify for reimbursement, navigate provincial or local procurement arrangements, enter individual hospital formularies, and ultimately be prescribed by physicians.[7] Before the introduction of national volume-based procurement, these access decisions remained territorially fragmented. Procurement arrangements varied across localities, and individual hospitals retained considerable influence over which products they purchased (e.g., Mossialos and Ge 2016; Lee and Burns 2017). This fragmentation created opportunities for local protectionism. Provincial drug-advertising inspections, for example, systematically discriminated against manufacturers from outside the province (Eberhardt, Wang, and Yu 2016). Yet access to a local market or admission to a hospital formulary did not guarantee actual use. Physicians served as the final gatekeepers and financial incentives could encourage them to favor more expensive versions of otherwise identical products (M. Chen et al. 2014; C. Chen et al. 2014). Manufacturers thus had to navigate both local protectionism in gaining market access and physician gatekeeping at the point of prescription.

Manufacturers responded by constructing overly elaborate commercialization infrastructures. The firm registry assembled for this study identifies more than 8,000 active pharmaceutical manufacturers and distributors across the country (Figure 4.2). An official retrospective reported that generics and modified versions of existing drugs accounted for 97% of marketed medicines (National Medical Products Administration 2018). In 2017, the drug regulator classified 294 drug varieties as "over-duplicated," meaning that each had at least 20 approved manufacturers and at least 20 manufacturers with observed sales (China Food and Drug Administration 2017). Manufactur-

7. China's health-insurance schemes are primarily publicly administered and constitute the principal source of pharmaceutical coverage. See Chapter 2 for a more detailed discussion of prescribing and reimbursement in China, and Chapter 3 for an account of how pharmaceutical sales were connected to public-hospital financing.

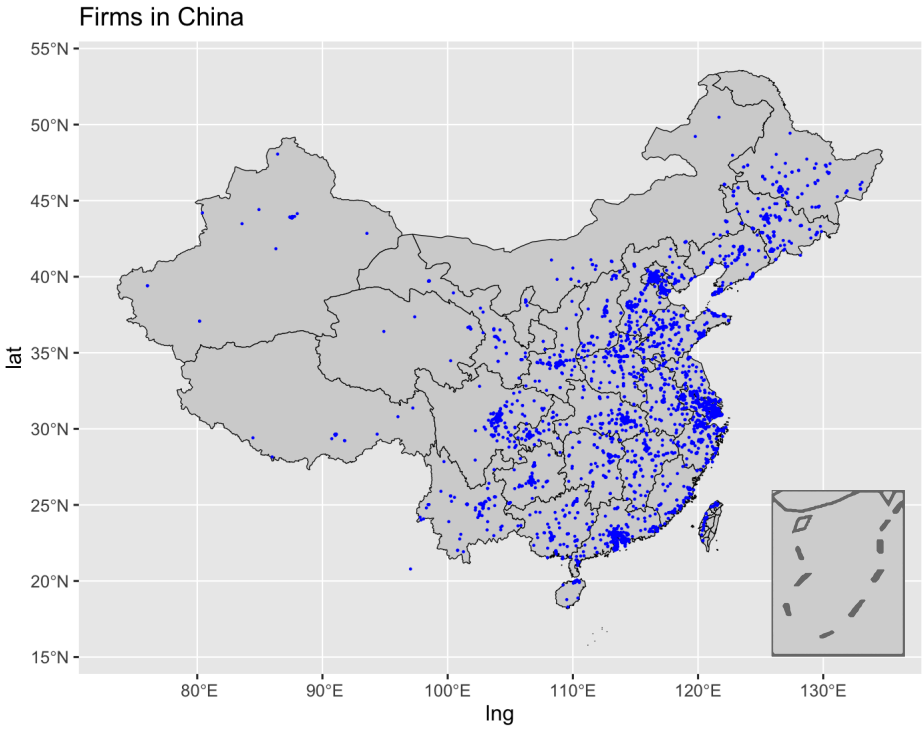


Figure 4.2: Geographic distribution of active pharmaceutical firms in China. *Notes*: Each point represents an actively registered pharmaceutical manufacturer or distributor. *Source*: Author's visualization based on self-collected firm-registration data from Qichacha.

ers worked through layers of distributors or built their own sales teams, cultivating relationships with hospitals and physicians. While many of these activities performed legitimate functions, such as physical distribution and physician education, the same distribution and promotional channels could conceal commissions and other informal payments intended to influence hospital access or prescribing (e.g., Ran et al. 2022; Yang 2016).

The resulting allocation of investment was privately rational but collectively costly. When numerous firms sold similar medicines, product quality was difficult to verify, and sales depended on administratively and organizationally controlled channels, an additional investment in distribution or promotion could yield a more immediate and predictable return than long-horizon research. At the sectoral level, this produced duplicative entry and substantial commercialization spending while weakening incentives to undertake original research. Pharmaceutical R&D expenditure amounted to only 1.41% of gross industrial output in 2011 (Qiu et al. 2014). Original innovation was not yet

the dominant route to commercial success. Firms could grow by reproducing known compounds and becoming better at getting them purchased and prescribed.

4.4.2 An Incomplete Transition: Innovation Without Commensurate Return

4.4.2.1 2015: Improved Regulatory Capacity

Recognizing the downsides to the old commercialization model, China launched a series of regulatory reforms beginning in 2015 to encourage domestic pharmaceutical innovation. Reform targeted the inefficient approval and evaluation process of new drug applications. The central government identified a large backlog of drug-registration applications, along with persistent concerns about the quality of application materials.

To address these problems, the State Council's *Opinions on Reforming the Review and Approval System for Drugs and Medical Devices* tightened the definition of a new drug. Under the previous standard, a drug could be classified as new simply because it had not yet been marketed in China, even if it was already available elsewhere. The reform reserved this designation for drugs not previously marketed either in China or abroad (State Council of the People's Republic of China 2015).

China's admission to the International Council for Harmonisation as a regulatory member in 2017 further aligned its novel drug standards with those used in established pharmaceutical markets. Membership committed Chinese regulators to implementing common technical guidelines and narrowed the gap between Chinese and international regulatory practices. This alignment helped make clinical evidence generated in China more legible to foreign regulators and potential commercial partners.

The administrative effects appeared quickly. According to the regulator's 2018 annual review report, the queue of applications awaiting review fell from a peak of nearly 22,000 in September 2015 to only 3,440 by the end of 2018. More than 90% of registration applications were being reviewed within the prescribed time limits (Center for Drug Evaluation, National Medical Products Administration 2019). The regulator also became more capable of processing a substantial volume of novel drug submissions. In 2018, the Center for Drug Evaluation accepted registration applications involving 264 Class 1 innovative-drug varieties (Center for Drug Evaluation, National Medical Products Administration 2019; Jia et al. 2023). These figures do not by themselves establish that regulatory reform caused the increase in innovative activity, but they show that the review system became substantially more capable of processing a growing innovative pipeline.

Together, these reforms made China's regulatory system for novel drugs more transparent, more supportive of genuine novelty, and more closely aligned with the standards of established pharmaceutical markets. Yet they primarily addressed whether a drug could proceed through clinical development and obtain regulatory approval. As discussed previously, approval did not guarantee commercial success. In fact, China's regulatory capacity for processing innovation was advancing much more rapidly than its domestic capacity for commercializing and rewarding it. More assets could enter and progress through the development pipeline, but the complementary institutions needed to finance that pipeline and generate returns from successful products remained incomplete.

4.4.2.2 Incomplete Progress in Commercialization of Novel Drugs

Commercialization of novel drugs remained a weak link in China's pharmaceutical sector even after the 2015 regulatory reform. Research estimates that China's novel drug market was worth only RMB 66 billion in 2015. High-priced novel drugs were largely excluded from public insurance, requiring patients to pay for them entirely out of pocket and thereby sharply constraining effective demand (Barwick, Xia, and Xia 2026).[8]

The Chinese state did try to address this demand-side weakness by reforming the country's National Reimbursement Drug List (NRDL). Through centralized negotiation, the government offered novel drugs access to the public insurance system in exchange for substantial price reductions. In 2017, 36 high-priced drugs were added to the reimbursement list after an average price reduction of 44%, with the largest reduction reaching 70% (National Healthcare Security Administration 2018a). The 2018 special negotiation for anticancer medicines considered 44 off-list exclusive products, and 17 were added to the list with payment standards 56.7% below their retail prices (Xinhua News Agency 2018). Reimbursement indeed expanded the potential market for novel drugs, but required firms to accept steep price concessions in return.

What further complicated the commercial value of novel drugs in China was again the fact that formal inclusion on the reimbursement list did not directly lead to sales. Hospitals retained responsibility for procurement and formulary decisions and varied in whether they chose to stock a particular reimbursed drug. Using procurement records from 887 public hospitals, H. Zhu et al. 2022 finds that while the average availability of 18 negotiated anticancer drugs increased from

8. For comparison, IMS Health data reported by EFPIA indicate that the United States accounted for 57% of worldwide sales in 2014 of new active ingredients launched between 2010 and 2014. The five largest European markets accounted for 25%, Japan for 7%, and China together with 20 other "pharmerging" markets for only 10% (European Federation of Pharmaceutical Industries and Associations 2015).

10.5% in 2015 to just over 30% in 2019, the average negotiated drug remained unavailable in nearly seven out of ten hospitals.

Even once drugs were approved, reimbursement typically arrived much later. Among novel medicines approved in China between 2018 and 2023, only 62% had obtained public reimbursement by July 2024. Among those that were reimbursed, the median interval between marketing authorization and reimbursement was 440 days (Wang et al. 2025). Because reimbursement decisions followed regulatory approval, they could not finance the preclinical and clinical development required to bring the same drug to market. Firms still had to fund development before knowing whether, when, and on what terms public reimbursement would become available.

These commercialization limitations were not necessarily caused by temporary administrative errors. They arose from the real financing constraints of a public insurance system committed to providing broad basic coverage. In a 2025 retrospective report, the National Healthcare Security Administration acknowledged a continuing gap between novel drug companies' price expectations and the payment capacity of basic medical insurance, as well as the limited development of alternative payment channels. It noted that resident basic medical insurance enrolled nearly one billion people but had annual per-capita financing of only approximately RMB 1,070, about two-thirds of which came from government subsidies. Some high-value innovative therapies simply remained beyond the immediate payment capacity of the basic insurance system (National Healthcare Security Administration 2025).

The emerging model represented a real improvement over the old commercialization model, but the transition was incomplete. This incompleteness is somewhat expected. Building a mature market encompassing public reimbursement, private insurance, hospital access, and multiple pricing and payment channels takes time and requires substantial fiscal resources. The resulting lag between China's expanding capacity to produce innovation and its domestic market's still-limited capacity to reward is a classic example of institutional delay.

4.4.2.3 2018: NVBP and the Compression of Generics

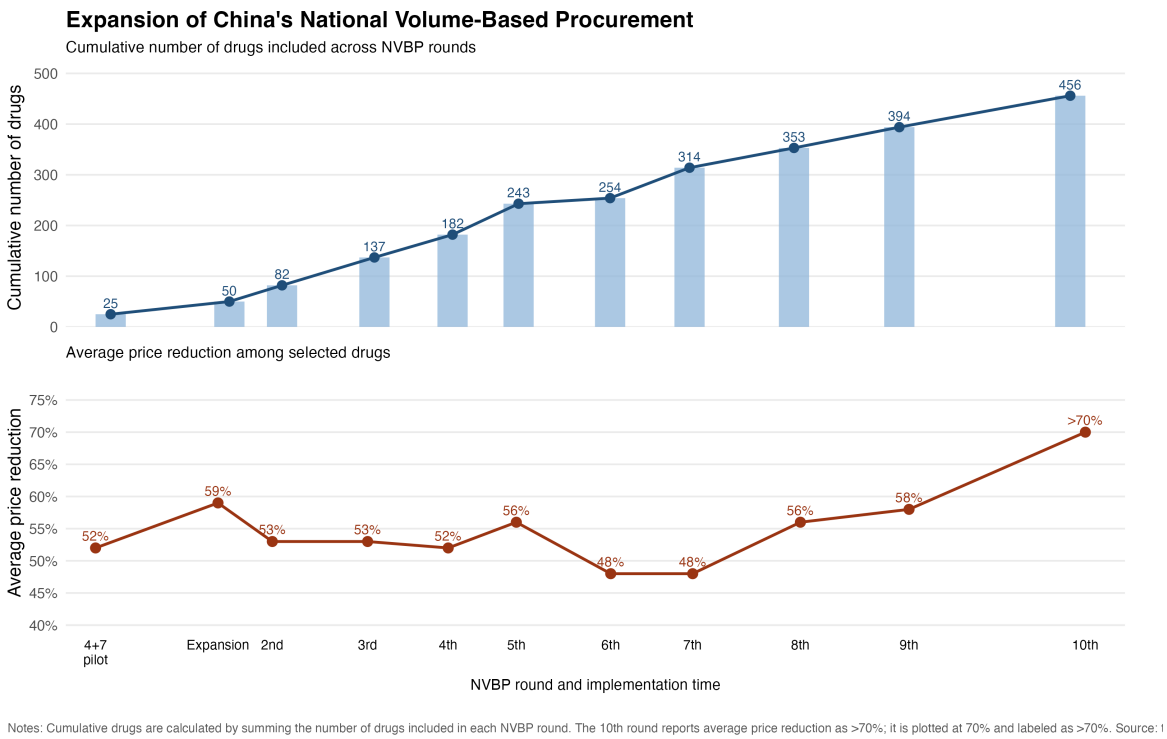
The incompleteness of the emerging innovation model became more detrimental for firms when the government moved even more aggressively against the old generic commercialization model. In November 2018, the state launched the "4+7" National Volume-Based Procurement (NVBP) pilot across four municipalities and seven major cities. The program pooled anticipated demand from public medical institutions and used competitive bidding to allocate a predetermined volume

of selected generic drugs. Winning manufacturers received access to a committed market, but only in exchange for substantially lower prices. For the products procured through the first round, winning prices fell by an average of 52%, with the largest reduction reaching 96% relative to the lowest 2017 purchase prices in the pilot cities (Joint Procurement Office 2018; National Healthcare Security Administration 2018b).

NVBP completely transformed the profit logic of China's pharmaceutical sector. Under the previous model, firms could use their accumulated sales networks to secure hospital access without product differentiation. NVBP instead allocated a substantial share of hospital demand for generic drugs through a centralized auction in which price largely determined which supplier won the bid. Hospitals were required to prioritize winning products and fulfill their committed purchasing volumes (Joint Procurement Office 2018), causing losing suppliers to lose much of the market for covered products. By the end of 2019, winning products accounted for 78% of purchases within the same generic names in the pilot regions (National Healthcare Security Administration 2020). Subsequent procurement rounds steadily expanded the number of covered drugs while continuing to produce substantial average price reductions (See Fig. 4.3). Firm-level research finds that NVBP reduced markups among chemical-drug manufacturers even as their sales expanded (Yan, Miao, and Cao 2025). Even for winning firms, greater volume did not necessarily preserve the rents previously available from generic drugs.

The procurement results triggered an immediate revaluation of China's pharmaceutical sector. Over the two trading days following the NVBP announcement, the combined market capitalization of the 287 stocks in the A-share pharmaceutical and biotechnology sector fell by approximately RMB 240 billion. Lepu Medical, Betta Pharmaceuticals, and several other firms reached the daily downward price limit, while more than twenty additional pharmaceutical stocks declined by over 5% (Liu 2018). Investors interpreted NVBP not merely as a price shock affecting the products included in the first procurement round, but as a broader threat to the profitability of the established generic commercialization model.

Although NVBP primarily targeted off-patent drugs rather than novel drugs, it profoundly reshaped firms' incentives and resources for innovation. The old generic commercialization model had directed investment toward sales rather than original research, yet profitable generic portfolios also provided recurring cash flows, organizational scale, and internal financing for firms beginning to develop novel drugs. Firms' own funds accounted for 92.73% of pharmaceutical R&D investment in 2011 (Qiu et al. 2014). By replacing competition through sales networks with centralized price competition and compressing generic margins, NVBP made differentiated products relatively



Notes: Cumulative drugs are calculated by summing the number of drugs included in each NVBP round. The 10th round reports average price reduction as >70%; it is plotted at 70% and labeled as >70%. Source: t

Figure 4.3: Expansion and Average Price Reductions under NVBP

more attractive while eroding a reliable source of financing for developing them. Reform therefore increased the pressure to innovate while weakening the commercial foundation from which firms could finance that costly and uncertain transition. Given the continuing limitations of China's domestic commercialization system for novel drugs, this combination led to a reform-induced support gap and increased the importance of alternative institutional support in sustaining innovation.

4.4.3 Activating the Latent Alternative: Cross-Border Out-Licensing

The preceding sections show how NVBP eroded the old commercialization model before China's domestic system could reliably reward innovation. This created a reform-induced support gap for Chinese pharmaceutical firms. Without another source of support, firms might have delayed upgrading, exhausted their resources, or exited during the transition. Yet, as Fig. 4.1 shows, Chinese drug innovation did not stall.

An alternative was already available through the global pharmaceutical market. For decades, developers of promising drug candidates had licensed their intellectual-property rights to firms better positioned to commercialize them (e.g., Arora, Fosfuri, and Gambardella 2001; Gans and Stern 2002). In a typical cross-border out-licensing agreement, often called a license-out deal for short, the originating firm grants a partner the right to develop or commercialize a drug in specified markets. In return, it receives some combination of upfront payments, milestone payments, royalties, and commitments to subsequent development. This chapter argues that out-licensing became an important source of alternative institutional support during China's domestic transition.

Out-licensing supplied several forms of support that remained difficult to obtain domestically. First, an upfront payment allowed a firm to realize part of a drug candidate's expected value before completing development and generating product sales. Second, milestone payments could provide further financing as development progressed, while royalties offered a claim on eventual foreign sales. Third, a foreign partner's willingness to commit capital provided external validation of the drug candidate to investors and other potential partners. Finally, the partner could also contribute regulatory expertise, clinical-development capacity, and commercialization networks in markets that the originating firm could not readily enter on its own. Out-licensing connected Chinese firms to financing and commercial capabilities that were already established in the global market, but absent in China's domestic market.

Chinese firms were not new to the international pharmaceutical market, but they had historically participated primarily as manufacturers or domestic licensees of foreign-developed products

rather than as licensors of their own innovative assets. This pattern began to change as the domestic transition accelerated. Cross-border license-out transactions increased after 2019 and expanded especially rapidly thereafter in both number and disclosed value (e.g., Jiang et al. 2024; Tan et al. 2025; IQVIA Institute for Human Data Science 2025). Regulatory reforms beginning in 2015 made Chinese drug candidates easier for foreign partners to evaluate and develop internationally (e.g., Jia et al. 2023; International Council for Harmonisation 2017; State Council of the People's Republic of China 2015). NVBP subsequently compressed generic rents, while the domestic market for novel drugs remained limited. Together, these changes made out-licensing both more feasible and more valuable to Chinese firms. China did not need to create the global licensing market from scratch. The domestic reforms simply enabled Chinese firms to make greater use of a market that already existed.

It is also important to note that out-licensing does not equate with firms leaving China's pharmaceutical system. Licensing agreements commonly divided rights by territory, allowing the originating firm to retain rights in China and continue conducting research at home while a foreign partner developed or commercialized the drug elsewhere. Firms could therefore obtain returns and support from abroad while sustaining innovative activity in China.

4.5 Data and Empirical Strategy

4.5.1 H_1 Firm Reorientation under Asymmetric Reform Pressure

The background section describes several reforms that played distinct roles in China's pharmaceutical transition. The regulatory reforms initiated in 2015 reduced barriers to novel drug development, while subsequent NRDL negotiations began constructing a domestic reimbursement pathway for novel drugs, albeit one that remained incomplete and required substantial price concessions. NVBP was the principal subtractive reform that produced a support gap. By sharply compressing the expected returns from the generic, sales-intensive model, it weakened an established source of firm revenue before domestic institutions could fully support the commercialization of novel drugs.

NVBP did not directly make innovation profitable. It instead changed the relative attractiveness of the established and emerging business models. Firms whose existing sales depended more heavily on the products and markets placed under procurement pressure faced a larger deterioration in the expected viability of their established model. Because the preceding regulatory reforms had already made formal drug development more feasible, these firms had a stronger incentive to redirect organizational attention and resources toward drug development. Less-exposed firms retained

greater scope to rely on their existing portfolios and therefore faced weaker pressure to reorient.

This yields the first testable implication of the theory: firms with greater pre-reform exposure to NVBP should exhibit a larger post-reform increase in formal drug-development activity. The prediction concerns attempted reorientation rather than eventual innovative success. Submitting a CDE registration represents a concrete commitment to development before the commercial outcome of the project is known. A firm may increase its development activity but subsequently fail to fully develop the product.

Measuring Pre-Reform Exposure To test this implication, I construct firm-level exposure using 4,102,268 sampled pharmaceutical sales records from a commercial dataset provided by Yaorongyun (药融云). The records cover sales by manufacturer, product, and geographic market between 2013 and 2023. Only records from 2013 through 2017 are used to construct reform exposure, ensuring that the measure precedes the announcement and implementation of NVBP. Manufacturer names and registered subsidiaries are reconciled and aggregated to their corporate parents using Qichacha (企查查) registration records.

The exposure measure is operationalized as the share of a firm's observed pre-reform sales generated by products in the ATC-3 categories[9] represented in the initial 4+7 procurement round and sold within the eleven pilot cities:

$$\mathit{Exposure}_i^{(4+7)\times\text{Pilot}} = \frac{\sum_p \sum_c \sum_{\tau=2013}^{2017} \mathit{Sales}_{ipc\tau} \times \mathbf{1}[\text{ATC3}(p) \in A_{4+7}] \times \mathbf{1}[c \in C_{4+7}]}{\sum_p \sum_c \sum_{\tau=2013}^{2017} \mathit{Sales}_{ipc\tau}}, \tag{4.1}$$

where p indexes pharmaceutical products, A_{4+7} denotes the set of ATC-3 categories represented among the drugs targeted by the initial procurement round, c indexes geographic markets, C_{4+7} denotes the eleven pilot cities, and τ indexes pre-reform years.

9. ATC-3 refers to the third level of the World Health Organization's Anatomical Therapeutic Chemical classification system, which groups drugs into pharmacological or therapeutic subgroups. Because the measure operates at the ATC-3 level, it captures commercial exposure to the broader product categories placed under procurement pressure rather than exact eligibility for a particular procurement contract. Products in the same ATC-3 category may differ in molecule, dosage form, quality certification, and bidding eligibility. The measure should therefore be interpreted as a predetermined proxy for commercial exposure, not as a measure of a firm's realized sales loss or procurement participation.

I construct two component measures for comparison. The first is the share of pre-reform sales generated by the relevant 4+7 ATC-3 categories across all geographic markets. The second is the share of pre-reform sales generated within the eleven pilot cities across all product categories. If the response reflects product-specific procurement pressure, exposure measures incorporating the targeted product categories should predict a larger post-reform increase in development activity, whereas pilot-city exposure alone need not do so.

All exposure measures are proportions bounded between zero and one. Before estimation, I rescaled each measure by 0.10 for interpretation. A one-unit increase in the exposure variable used in the regressions represents a 10-percentage-point increase in the corresponding pre-reform sales share.

Measuring Firm-Level Reorientation The outcome data come from registrations recorded by China's Center for Drug Evaluation (CDE). I link applicants appearing in the registration records to their corporate parents and aggregate their activity into a quarterly firm panel. When a registration lists multiple applicants, each applicant receives an equal share, so that applicant weights sum to one within each registration. These weights are then aggregated to the corporate-parent level.

I use two complementary outcome measures. The first is an indicator equal to one if a firm records any Phase I–III activity in a quarter and zero otherwise. This measure captures quarterly participation in the clinical-development activity most directly relevant to innovation and is estimated using a linear probability model. Because the phase-specific registration records begin in 2016, this analysis covers 2016Q1 through 2023Q4.

The second outcome is the weighted total number of CDE registrations associated with a firm in a quarter. This measure includes clinical-development registrations as well as bioequivalence and consistency-evaluation activity. The weighted count therefore captures a broader movement toward formal drug-development activity rather than novel-drug development alone. I estimate the count in levels for the headline specification. I also use the natural logarithm of one plus the weighted total count in the exposure-definition comparisons. Adding one retains firm-quarters with no registrations, while the logarithmic transformation reduces the influence of firms with unusually large development pipelines. The total-CDE analyses cover 2013Q1 through 2023Q4.

Accordingly, Y_{iq} in Equation 4.2 denotes the Phase I–III participation indicator, the weighted total CDE count, or the logged weighted total CDE count, depending on the specification.

Continuous-Exposure Difference-in-Differences Design I estimate the following continuous-exposure difference-in-differences model:

$$Y_{iq} = \alpha_i + \lambda_q + \beta \left(\widetilde{Exposure}_i^{\text{Pre}} \times PostNVBP_q \right) + \varepsilon_{iq}, \tag{4.2}$$

where i indexes firms and q indexes calendar quarters. α_i denotes firm fixed effects and λ_q denotes calendar-quarter fixed effects, which absorb regulatory changes, macroeconomic conditions, and industry-wide changes affecting all pharmaceutical firms. $PostNVBP_q$ equals one beginning in the first quarter of 2019, the first full quarter following the initial 4+7 procurement. Standard errors are clustered at the firm level.

The coefficient of interest is β. Because the exposure measure is expressed in 10-percentage-point units, β estimates the differential post-2019 change associated with a 10-percentage-point increase in a firm's pre-reform sales exposure. The theoretical prediction is $\beta > 0$ as firms more dependent on the product categories and geographic markets placed under procurement pressure should exhibit a larger increase in formal drug-development activity than less-exposed firms.

For substantive interpretation, I also translate each coefficient into the estimated difference between a firm with no exposure and a firm at the mean exposure among those positively exposed. For the preferred measure of targeted-product exposure within the pilot cities, this benchmark is 44.8% of pre-reform sales. For the participation and level-count specifications, I report both the absolute difference and its magnitude relative to the corresponding pre-NVBP outcome mean.

I provide two additional comparisons that probe important alternative explanations. First, I estimate the model separately using targeted-category exposure and pilot-city exposure. This assesses whether the observed relationship is tied to the products placed under procurement pressure or merely reflects post-2019 changes among firms operating heavily in large urban markets. Second, I compare exposed firms not focused on traditional Chinese medicine with firms concentrated in traditional Chinese medicine (TCM), whose principal portfolios were largely insulated from the initial procurement program. This placebo comparison evaluates whether the same post-2019 pattern appears among firms that should have faced substantially less direct procurement pressure.

4.5.2 H_2 Out-Licensing and the Persistence of Innovation

The first test examines whether reform pressure prompted firms to reorient toward drug development. The second implication concerns whether firms could sustain that reorientation. Beginning a

drug-development project does not ensure its continuation. Clinical development requires ongoing financing, technical validation, and a credible route to commercialization, all of which remained difficult to secure domestically during the reform-induced support gap.

The previous section identifies cross-border out-licensing as a channel through which firms could obtain these forms of support. The prediction is not that a license-out agreement creates innovation from nothing. Rather, among firms that entered the transaction period with similar development trajectories and commercial characteristics, those securing a license-out deal should subsequently sustain more domestic innovation activity than those that had not activated this channel.

Treatment and Matched Risk Sets The main identification challenge is that license-out agreements are not randomly assigned. Overseas partners select commercially promising assets, and originating firms must already possess sufficiently developed and legible pipelines to complete a transaction. A simple comparison between firms with and without license-out agreements would risk attributing their preexisting differences to the transactions themselves.

To make the comparison more credible, I combine risk-set matching with a stacked difference-in-differences design. I construct treatment timing from a transaction-level dataset of cross-border pharmaceutical license agreements from Yaorongyun. The records identify the participating firms, transaction date, licensed asset, stage of development, therapeutic area, licensed territory, and disclosed deal value. The initial review covered 329 candidate transaction records. After validating individual deals and screening corporate-ownership relationships, I assigned 63 qualifying transactions to 29 originating firms and 26 listed corporate parents.[10] For each corporate parent, the treatment date is the quarter of its first qualifying license-out recorded in the data. The analysis considers firms whose first qualifying transaction occurred in or after 2019. Firms that had already completed a qualifying license-out before 2019 are not eligible to serve as either treated firms or controls.

For each treated firm, I construct a separate matched stack s, with the quarter of its first license-out denoted by g_s. The matching procedure is conducted separately for each of three post-treatment horizons: four, eight, and twelve quarters. An eligible control must have complete outcome data over the corresponding event window, remain untreated in quarter g_s, and not complete its own

10. A transaction qualifies when a Chinese pharmaceutical originator grants an overseas counterparty development or commercialization rights and the agreement can be assigned to a specific quarter. A transaction completed by a subsidiary is attributed to its listed parent only when the ownership relationship existed at the time of the deal. Minority holdings, sibling companies, and acquisitions completed after the transaction are not used to assign treatment.

first license-out before the end of that post-treatment window. Firms treated later may therefore serve as controls, but only when their first transaction occurs after the focal firm's entire follow-up period.

Within each risk set, I match the focal firm to the three control firms with the most similar pre-transaction development histories, commercial characteristics, and exposure to NVBP.[11] The resulting comparison is between a firm completing its first license-out and firms that, immediately before the transaction, had followed similar development paths and occupied similar commercial positions but had not yet completed such an agreement. It does not compare license-out firms with the remainder of the pharmaceutical industry as a whole.

Measuring Subsequent Domestic Innovation The outcome data come from clinical-trial registrations recorded by the Center for Drug Evaluation. As in the H_1 analysis, applicants are linked to their corporate parents, and registrations are aggregated into a quarterly firm panel covering 2016 through 2024. When a registration lists multiple applicants, each receives an equal share so that applicant weights sum to one within the registration.

The primary outcome is the natural logarithm of one plus weighted Phase I–III CDE activity:

$$Y_{isq} = \ln\left(1 + \textit{Phase I–III CDE}_{iq}\right). \tag{4.3}$$

This measure focuses on clinical development within China rather than the bioequivalence and consistency-evaluation activity associated with generic drugs. Adding one retains quarters with no new registrations, and the logarithmic transformation reduces the influence of firms with unusually large pipelines. Because the measure records new registrations, it captures firms' continued addition of projects to the formal development pipeline rather than ongoing work on every existing project.

I also estimate the model using the weighted Phase I–III count in levels with OLS and PPML. The level specification provides an absolute count interpretation, while PPML provides a count-

11. Development history is measured during the eight pre-transaction quarters using total Phase I–III CDE activity, Phase I–III activity during the most recent four quarters, the number of quarters with positive Phase I–III activity, the linear pre-treatment trend, and total BE activity. Commercial characteristics include pre-reform sales, the TCM share of pre-reform sales, exposure to the ATC-3 categories represented in the initial 4+7 round, dependence on the eleven pilot-city markets, and exposure to the targeted categories within those markets. These sales and exposure measures come from the same 2013–2017 Yaorongyun records and corporate-parent crosswalk used in the H_1 analysis. Matching is based on Euclidean distance after standardizing the covariates so that differences in their original scales do not determine the match.

model comparison that retains zero outcomes.

As outcome-specificity checks, I repeat the analysis using all clinical CDE activity and registrations in Phases II and III separately. I also use BE registrations as a comparison outcome. If license-out agreements specifically help firms sustain innovative clinical development, the positive relationship should appear in the clinical outcomes but not in BE activity.

Stacked Difference-in-Differences Estimation For each post-treatment horizon H, I estimate the following model:

$$Y_{isq} = \alpha_{is} + \lambda_{sq} + \beta_H \left(\mathit{Treated}_{is} \times \mathit{Post}_{sq}^{H} \right) + \varepsilon_{isq}, \tag{4.4}$$

where i indexes firms, s indexes matched stacks, and q indexes calendar quarters. $\mathit{Treated}_{is}$ equals one for the focal license-out firm in stack s and zero for its three matched controls. Each specification includes the eight quarters preceding the focal transaction and one of three post-treatment windows: event quarters $+1$ through $+4$, $+1$ through $+8$, or $+1$ through $+12$. Post_{sq}^{H} equals one during event quarters $+1$ through $+H$ and zero during event quarters -8 through -1.[12]

The matched-stack-by-firm fixed effects, α_{is}, absorb persistent differences between the focal firm and each control within a particular matched comparison. The matched-stack-by-calendar-quarter fixed effects, λ_{sq}, absorb regulatory, macroeconomic, and industry-wide shocks occurring at the same calendar time for all firms in that stack. The focal firm receives a weight of one, and its three controls each receive a weight of $\frac{1}{3}$, giving the treated and control sides equal total weight within each stack. Standard errors are clustered by the original firm identifier to account for firms that appear in more than one matched stack.

The coefficient of interest is β_H. It captures how much more the focal firm's development activity changed after its first license-out than the activity of its matched controls over the same period. The theoretical prediction is $\beta_H > 0$: firms activating the external licensing channel should sustain more subsequent clinical-development activity than otherwise comparable firms that have not activated it.

12. The transaction quarter is excluded from the pooled specifications because an agreement completed partway through a quarter cannot be expected to affect development activity over that entire quarter. Because the three post-treatment windows require different amounts of follow-up, they contain different treatment cohorts. Their estimates should therefore not be interpreted as the effect for a single cohort accumulating mechanically over time.

4.6 Results

4.6.1 H_1 Results: NVBP Exposure and Drug-Development Activity

Table 4.1: Pre-Reform NVBP Exposure and Post-NVBP Drug-Development Activity

	(1)	(2)	(3)	(4)	(5)
Outcome	Phase I–III	Total CDE			
Form	Indicator	Log count	Count	Log count	Log count
Estimator	LPM	OLS	OLS	OLS	OLS
Post-NVBP × 4+7 ATC exposure in pilot cities	0.0010*	0.0034***	0.0055**		
	(0.0006)	(0.0011)	(0.0022)		
Post-NVBP × 4+7 ATC exposure				0.0046***	
				(0.0009)	
Post-NVBP × pilot-city exposure					0.0006
					(0.0009)
Mean positive exposure	44.8%	44.8%	44.8%	82.0%	52.6%
Effect relative to pre-NVBP mean	**+17.4%**	–	**+26.4%**	–	–
Estimated change in registration activity	–	+1.53%	–	+3.82%	+0.34%
95% CI	$[-2.5\%, 37.3\%]$	$[0.55\%, 2.52\%]$	$[5.1\%, 47.6\%]$	$[2.36\%, 5.31\%]$	$[-0.62\%, 1.31\%]$
Absolute effect per firm-quarter	+0.43 pp	–	+0.0245	–	–
Annual difference per 100 firms	–	–	+9.8	–	–
Pre-NVBP outcome mean	2.46%	0.0465	0.0929	0.0465	0.0465
Firm fixed effects	Yes	Yes	Yes	Yes	Yes
Quarter fixed effects	Yes	Yes	Yes	Yes	Yes
Firms	1,035	1,035	1,035	1,035	1,035
Observations	33,120	45,540	45,540	45,540	45,540
Analysis period	2016–2023	2013–2023	2013–2023	2013–2023	2013–2023

Notes: The unit of analysis is the firm-quarter. Exposure measures are constructed from 2013–2017 sales. Each measure is rescaled so that one unit represents a 10-percentage-point increase in the corresponding pre-reform sales share. Post-NVBP equals one beginning in 2019Q1. Column 1 is a linear probability model in which the dependent variable equals one if the firm records any Phase I–III activity during the quarter. Columns 2, 4, and 5 use the natural logarithm of one plus weighted total CDE registrations. Column 3 uses the weighted total CDE count in levels. Substantive effects compare firms with no exposure against firms at the mean exposure among those positively exposed. For Columns 1 and 3, the effects are expressed relative to the pre-NVBP outcome mean and are also reported in absolute terms. For Columns 2, 4, and 5, the logged estimates are converted into approximate percentage differences in CDE registration activity. Brackets report 95% confidence intervals for the corresponding substantive effects. All models include firm and calendar-quarter fixed effects. Firm-clustered standard errors are reported in parentheses. Significance levels: *** $p < 0.01$, ** $p < 0.05$, * $p < 0.10$.

Table 4.1 presents the main results for H_1. Firms whose pre-reform sales depended more heavily on the product categories targeted by NVBP subsequently exhibited larger increases in formal drug-development activity. This relationship appears under both measures incorporating targeted-product exposure. By contrast, exposure to the eleven pilot cities alone is not associated with a statistically significant change, suggesting that the result reflects pressure on firms' product portfolios rather than a general post-2019 trend among firms operating in the pilot cities.

Column 3 supplies the main result for total CDE activity. A 10-percentage-point increase in exposure to targeted product categories within the pilot cities is associated with 0.0055 additional weighted CDE registrations per firm-quarter after NVBP. Compared with firms facing no exposure, firms at the average exposure among those affected—44.8% of pre-reform sales—are estimated to record approximately 9.8 additional weighted registrations across 100 firms observed for one year. Relative to the pre-NVBP mean of 0.0929 registrations per firm-quarter, the estimated difference is 26.4% of baseline activity, with a 95% confidence interval ranging from 5.1% to 47.6%.

Column 1 provides the more innovation-specific result. Compared with firms facing no exposure, firms at the same 44.8% benchmark are estimated to have a 0.43-percentage-point higher quarterly probability of recording any Phase I–III activity. Relative to the 2.46% pre-NVBP participation probability, this point estimate represents a 17.4% increase, significant at the 10% level ($p = 0.0876$).

The log specifications produce the same exposure-specific pattern. After NVBP, firms at the average positive exposure to targeted products within the pilot cities are estimated to have 1.53% more CDE registration activity than unexposed firms. The corresponding difference is 3.82% for firms at the average positive exposure to targeted ATC-3 categories across all markets. By contrast, the estimated difference associated with average positive pilot-city exposure alone is 0.34% and is not statistically significant.

Taken together, the results are consistent with the theoretical prediction. Firms facing greater procurement pressure on their established portfolios subsequently undertook more formal drug-development activity, whereas geographic exposure without targeted-product exposure produced no comparable response.

4.6.1.1 Placebo Test: Traditional Chinese Medicine

The continuous-exposure design compares firms facing different degrees of procurement pressure within the pharmaceutical industry. As an additional placebo-sector comparison, I compare at-risk

non-TCM firms with firms concentrated in traditional Chinese medicine. The initial 4+7 pilot and the early national procurement rounds focused primarily on chemical drugs. TCM-focused firms were largely insulated from the direct pressure that NVBP placed on chemical-generic portfolios.[13]

I estimate the following specification:

$$Y_{iq} = \alpha_i + \lambda_q + \delta \left(\mathit{AtRiskNonTCM}_i \times \mathit{PostNVBP}_q \right) + \varepsilon_{iq}. \tag{4.5}$$

The coefficient δ captures whether the post-2019 change in CDE registration activity among at-risk non-TCM firms differed from the corresponding change among TCM-focused firms. If the main result merely reflected an industry-wide increase in drug-development activity after 2019, the two groups should not exhibit systematically different changes.

Table 4.2: Placebo-Sector Comparison: Traditional Chinese Medicine Firms

	(1)	(2)
Outcome	$\ln(1 + \text{CDE})$	Weighted CDE count
Estimator	OLS	OLS
Post-NVBP × at-risk non-TCM firm	0.0853***	0.1808***
	(0.0100)	(0.0275)
TCM pre-NVBP mean	0.0077	0.0119 per quarter
Estimated change in registration activity	**+8.90%**	–
Annual difference per 100 firms	–	**+72.3**
95% CI	[6.79%, 11.06%]	[50.8, 93.9]
Firm fixed effects	Yes	Yes
Quarter fixed effects	Yes	Yes
Firms	762	762
Observations	33,528	33,528

Notes: The unit of analysis is the firm-quarter. The sample compares non-TCM firms with positive pre-reform exposure to the relevant 4+7 ATC-3 categories within the pilot cities against TCM-focused firms. TCM-focused firms constitute the omitted group. Post-NVBP equals one beginning in 2019Q1. The logged estimate in Column 1 is converted into an approximate percentage difference in CDE registration activity. The annual difference in Column 2 converts the quarterly count estimate into additional weighted registrations per 100 firm-years. Brackets report 95% confidence intervals for the corresponding substantive effects. Both models include firm and calendar-quarter fixed effects. Firm-clustered standard errors are reported in parentheses. Significance levels: *** $p < 0.01$, ** $p < 0.05$, * $p < 0.10$.

13. A firm is classified as TCM-focused if TCM products account for more than 50% of its pre-NVBP sales portfolio. At-risk non-TCM firms are non-TCM firms with positive pre-reform exposure to the relevant 4+7 ATC-3 categories within the pilot cities.

Table 4.2 shows that at-risk non-TCM firms experienced a larger post-NVBP change in CDE registration activity than TCM-focused firms. Relative to TCM-focused firms, the post-NVBP change among at-risk non-TCM firms was larger by 0.1808 weighted CDE registrations per firm-quarter, or approximately 0.723 registrations per firm-year. Across 100 firms observed for one year, this corresponds to approximately 72.3 additional weighted registrations, with a 95% confidence interval ranging from 50.8 to 93.9. Column 1 produces the same directional conclusion: at-risk non-TCM firms experienced an estimated 8.90% larger post-NVBP increase in CDE registration activity than TCM-focused firms, with a 95% confidence interval ranging from 6.79% to 11.06%.

This comparison reinforces the main pattern. Firms whose established portfolios were more directly exposed to procurement pressure subsequently shifted more strongly toward formal drug development than firms in the comparatively insulated TCM sector. This divergence is inconsistent with a post-2019 increase common to the pharmaceutical industry as a whole.

4.6.2 H_2 Results: License-Out Activation and Domestic Clinical Development

Table 4.3 presents the results for H_2. Across all three follow-up windows, firms securing a license-out deal exhibited a larger post-transaction increase in domestic Phase I–III CDE activity than their matched controls.

The level estimates in Panel A provide the most intuitive interpretation. During the first four complete quarters after the transaction, the differential increase was 0.603 weighted Phase I–III registrations per firm-quarter. Across the first post-transaction year, this amounts to approximately 2.4 additional weighted registrations per license-out firm relative to the change among matched controls. The corresponding cumulative differences are approximately 5.0 registrations over eight quarters and 10.2 registrations over twelve quarters. The estimates using the transformed outcome and PPML produce the same general conclusion.[14]

Panel B examines whether this difference is actually concentrated in innovative clinical development. The broader measure of clinical CDE activity closely follows the primary outcome. Among the phase-specific outcomes, the estimated difference is positive for Phase II trials across all three windows. Phase III activity does not differ detectably during the shorter windows but becomes positive and statistically significant in the twelve-quarter sample. This pattern is consistent with license-out firms continuing development into more advanced clinical stages, although the

14. Because these longer windows contain different and progressively smaller sets of treated firms, the coefficients should not be interpreted as the same effect growing mechanically over time. They instead show that the positive relationship appears in samples with both shorter and longer follow-up.

Table 4.3: License-Out Activation and Subsequent CDE Registration Activity

Post-treatment window	+1 to +4	+1 to +8	+1 to +12
Panel A. Phase I–III CDE activity			
License-out × post: ln(1 + weighted CDE), OLS	0.1871*	0.2331**	0.3310**
	(0.0997)	(0.0985)	(0.1295)
License-out × post: weighted CDE count, OLS	0.6030**	0.6293**	0.8503**
	(0.2695)	(0.2420)	(0.2635)
Implied cumulative difference over window	**+2.4**	**+5.0**	**+10.2**
License-out × post: weighted CDE count, PPML	0.5681**	0.4622**	0.4963**
	(0.2315)	(0.1810)	(0.2405)
Panel B. Outcome specificity, ln(1 + *weighted CDE*)*, OLS*			
All clinical CDE activity	0.1738*	0.2188*	0.3131**
	(0.0990)	(0.1031)	(0.1307)
Phase II CDE activity	0.0730***	0.0922*	0.1554***
	(0.0204)	(0.0446)	(0.0445)
Phase III CDE activity	-0.0107	0.0563	0.0982**
	(0.0178)	(0.0490)	(0.0418)
BE activity (placebo outcome)	-0.2314	-0.2488	-0.2385
	(0.1411)	(0.2146)	(0.2703)
Matched-stack-by-firm fixed effects	Yes	Yes	Yes
Matched-stack-by-calendar-quarter fixed effects	Yes	Yes	Yes
OLS observations	288	256	240
PPML observations	188	188	236

Notes: The unit of analysis is the firm-quarter within a matched stack. Each treated firm is matched to three firms from its contemporaneous risk set. All specifications include eight pre-treatment quarters. The transaction quarter is excluded, and the post-treatment period begins in the first complete quarter after the transaction. Treated firms receive a weight of one, while each matched control receives a weight of one-third. The three columns include firms with sufficient follow-up for the stated horizon and therefore contain different treatment cohorts. The implied cumulative differences multiply the OLS level coefficient by the number of post-treatment quarters in the corresponding column and are rounded to one decimal place; they are derived quantities rather than separately estimated coefficients. All models include matched-stack-by-firm and matched-stack-by-calendar-quarter fixed effects. Standard errors clustered by the original firm are reported in parentheses. PPML estimates proportional changes in the conditional mean of the weighted CDE count without applying a logarithmic transformation. Its observation counts differ because fixed-effect groups without usable outcome variation do not contribute to the likelihood. Significance levels: *** $p < 0.01$, ** $p < 0.05$, * $p < 0.10$.

estimates do not track the progression of individual drug candidates.

By contrast, BE registrations show no comparable positive difference at any horizon. Because BE activity is associated primarily with generic-drug development rather than innovative clinical pipelines, this placebo result helps distinguish the finding from a general post-transaction increase in all forms of regulatory activity. The difference is concentrated in the clinical-development outcomes most relevant to firms' innovative pipelines.

Taken together, the results support H_2. Among firms entering the transaction period with similar observed development histories, commercial characteristics, and exposure to NVBP, those activating the cross-border licensing channel subsequently sustained more domestic clinical-development activity than those that had not activated it. This pattern is consistent with the proposed bridging mechanism: external licensing support helps firms maintain their innovative pipelines during the period in which domestic institutions provided an incomplete route to financing and commercialization.

4.7 Qualitative Case Study

4.7.1 From Fast Follower to Innovation Giant: Jiangsu Hengrui Pharma

Jiangsu Hengrui Pharma provides a firm-level view of both stages of the transition examined in this chapter. Hengrui grew out of a state-owned factory that produced low-value antiseptics such as mercurochrome (*hongyaoshui*) and gentian violet (*ziyaoshui*). It first became one of China's most successful producers of high-value generic drugs and later emerged as a major developer of innovative medicines (Liu and Wu 2021). Its experience shows how reform made the generic-profit model increasingly untenable and how overseas licensing subsequently helped the company sustain its transition toward innovation.

Hengrui's predecessor, the Lianyungang Pharmaceutical Factory, was established in 1970 under local public control and primarily manufactured antiseptics, ordinary antibiotics, and other low-value products (Liu and Wu 2021). When the 32-year-old Sun Piaoyang became factory director in 1990, it had slightly more than 300 employees and earned approximately RMB 80,000 in annual profit (Liu and Wu 2021). Recalling those years, Sun described producing tablets that sold for one fen (one cent) and yielded only one li (0.1 cent) in profit. However hard the factory worked, he concluded, "nothing would change" without finding another route (Tian 2022).

Sun led the factory out of this predicament through a fast-follow strategy. Rather than discover

entirely new drugs, Hengrui sought to develop domestic versions of established foreign medicines, focusing on oncology products that were technically difficult to reproduce (Tian 2022). Sun borrowed RMB 3 million to acquire the rights to a VP-16 formulation, and the resulting product reportedly helped the factory generate RMB 50 million in sales the following year (Liu and Wu 2021). By entering less crowded and more technically demanding markets, Hengrui accumulated capital as well as experience in oncology, manufacturing, and commercialization. The company listed in Shanghai in 2000 and subsequently passed from public to private control (Jiangsu Hengrui Pharmaceuticals Co., Ltd. 2025). These resources and capabilities provided the foundation for a more ambitious transition.

Hengrui began a deliberate move toward novel drug development in 2004 through what the company called its "two-legged" strategy (Liu and Wu 2021). One leg remained in generics, while the other extended into novel-drug development. Revenue from generics would finance the longer and riskier process of developing proprietary drugs. The initial transition placed Hengrui's finances under considerable pressure. Operations director Jiang Yong compared novel drug development to farming only to reject the analogy: hard work did not ensure a harvest, and a failed clinical project could erase years of investment (Liu and Wu 2021).

At this stage, Hengrui's innovative strategy remained primarily fast-follow. The company generally pursued compounds based on mechanisms or products first developed abroad and relied on its domestic development and commercialization advantages to bring them to the Chinese market. This approach produced imrecoxib, approved in 2011, followed by apatinib in 2014, pyrotinib in 2018, and camrelizumab in 2019 (Jiangsu Hengrui Pharmaceuticals Co., Ltd. 2025). These products qualified as innovative drugs under Chinese regulatory classifications, but they largely represented follow-on or incremental innovation rather than first-in-class discovery. Even so, developing them gave Hengrui research capabilities that most conventional generic manufacturers lacked. Generics and innovation were not yet competing businesses. Profits from the former served as Hengrui's internal bridge to the latter.

NVBP destabilized the financing logic behind this arrangement. The reform compressed the generic earnings that had supported Hengrui's research, making even comparatively less costly fast-follow development more difficult to sustain through internal cash flows. But at the same time, it also strengthened management's conviction that incremental imitation alone offered little protection from intensifying price competition. Hengrui reported at an industry conference that it had stopped initiating ordinary generic projects in the summer of 2018, several months before the first "4+7" procurement document was issued on November 15 (Zhu 2019; Joint Procurement Office 2018).

The timing suggests that management had already begun anticipating deterioration in the generic model. NVBP confirmed the direction of the change and made it more urgent. In October 2019, Sun declared that Hengrui should retain only innovative drugs and high-value generics protected by genuine technical barriers. Spending elsewhere could be reduced, he said, but investment in innovation "could only increase, not decrease" (Zhu 2019).

Management did not assume that revenue from innovative drugs would immediately replace declining generic profits. In March 2019, Sun acknowledged that whether innovative drugs would produce high returns in China "remained to be seen" (Securities Daily (证券日报) 2019). He singled out the limited development of commercial health insurance and warned that weaknesses in reimbursement would constrain continued innovation. In his words, "without returns, a virtuous cycle cannot form" (Securities Daily (证券日报) 2019). Hengrui confronted the reform-induced support gap in a particularly clear form. The company possessed innovative capabilities and products, but the established business financing their development was being compressed before management believed the domestic market could reliably reward them.

The anticipated pressure became a realized financial shock in 2021. By the end of that year, 28 Hengrui generics had been included in national procurement rounds. 18 were selected, with an average price reduction of 73% (Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江苏恒瑞医药股份有限公司) 2022). Selection allowed Hengrui to preserve some sales volume, leaving it better positioned than unsuccessful bidders, but it did not preserve its previous margins. Sales from 6 products affected by the third procurement round fell by 55%, while sales from eight products affected by the fifth round fell by 37% (Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江苏恒瑞医药股份有限公司) 2022). Hengrui's total revenue declined by 6.59% and its net profit by 28.41%, producing the first simultaneous decline in both measures since its 2000 listing (Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江苏恒瑞医药股份有限公司) 2022).

In a December 2021 public conversation, Sun called procurement an unavoidable "painful transition." Hengrui had prepared for it, but the concentrated effects were more severe than management expected (E-Pharma Manager (E 药经理人) 2021). "Generics fall rapidly from their peak," he explained, "while innovative drugs grow only gradually" (E-Pharma Manager (E 药经理人) 2021). The two trajectories could not converge quickly enough to eliminate the pressure between them. Hengrui had prepared innovative drugs for years, but their growth was neither fast nor predictable enough to replace the earnings disappearing from its established business.

Hengrui responded by reallocating resources rather than retreating from drug development.

Its R&D investment increased by 24.34% in 2021 to RMB 6.20 billion, equivalent to 23.95% of revenue, even as total revenue and profits declined (Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江苏恒瑞医药股份有限公司) 2022). The company reduced its sales force from 17,138 to 13,208 employees during 2021 and eliminated another 2,300 positions during the first half of 2022. Over approximately the same period, its R&D workforce grew from around 4,700 employees in 2020 to more than 5,300 by mid-2022 (National Business Daily (每日经济新闻) 2023). Hengrui's efforts paid off. Three innovative drugs were approved in 2021, bringing the total to ten. More than 60 innovative candidates and 250 clinical studies remained under development in China and abroad (Jiangsu Hengrui Pharmaceuticals Co., Ltd. (江苏恒瑞医药股份有限公司) 2022).

By 2023, Sun described the strategic danger of remaining dependent on generics even more starkly: "If we were still making generics, one procurement round tomorrow could reduce [the business] to zero" (National Business Daily (每日经济新闻) 2023). The global market offered a possible revenue alternative, although Hengrui was not entirely new to it. The company had tested overseas licensing as early as 2015, when Incyte paid $25 million upfront for rights to develop camrelizumab outside mainland China, Hong Kong, Macao, and Taiwan (Incyte Corporation 2015). Sun explained at the time that combining the two companies' resources could accelerate the drug's development. Incyte subsequently returned the rights and terminated the agreement in 2018 (Incyte Corporation 2015; BioCentury 2018). Although unsuccessful, the transaction shows that the external channel already existed and that Hengrui had begun experimenting with it.

Sun was nonetheless cautious about attempting to reproduce the entire global development system within Hengrui. Direct overseas development required large expenditures with highly uncertain returns, he explained. The company had instead moved toward "strengthening external cooperation" while continuing to concentrate its own resources on its domestic business (National Business Daily (每日经济新闻) 2023). Hengrui did not abandon domestic drug development in favor of expansion abroad. It increasingly relied on foreign partners to perform parts of overseas development and commercialization that would have been costly to build for Hengrui.

Hengrui began using this channel much more systematically after the procurement shock. In 2023, it concluded five overseas licensing agreements with a combined potential value exceeding $4 billion (Jiangsu Hengrui Pharmaceuticals Co., Ltd. 2026). An October agreement with Merck KGaA provided EUR 160 million upfront for two oncology programs. Contingent payments could raise the total value to EUR 1.4 billion(Merck KGaA 2023). In May 2024, Hengrui licensed three metabolic-drug programs outside Greater China to the newly created company that became Kailera. In return, it received $110 million in upfront and near-term payments, a 19.9% equity stake,

royalties, and contingent milestones (Cooley LLP 2024). In July 2025, GSK agreed to pay $500 million upfront for a clinical-stage respiratory program and options on as many as eleven additional programs. The approximately $12 billion in announced milestones remained conditional on GSK exercising those options and the programs meeting subsequent development, regulatory, and commercial targets (GSK plc 2025).

The structure of these agreements allowed Hengrui to monetize foreign rights without surrendering its domestic pipeline. The Kailera and GSK transactions excluded Greater China, leaving Hengrui in control of development and commercialization in its principal domestic market (Cooley LLP 2024; GSK plc 2025). Under the GSK collaboration, Hengrui also remained responsible for advancing the optioned programs through Phase I, including producing clinical data outside China, before GSK could assume their further global development (GSK plc 2025). These arrangements supported continued activity within Hengrui rather than simply transferring completed assets abroad.

Hengrui's vice president He Feng explicitly described successful license-outs as a way to share project risk with foreign companies and use upfront and milestone income to "compensate R&D expenditure" (Lu 2025). The transactions also created a channel for learning. During due diligence, multinational partners posed hundreds or thousands of questions covering drug discovery, clinical development, and manufacturing. Preparing answers exposed Chinese teams to their partners' standards, judgments, and regulatory experience (Lu 2025). License-outs provided current income, external validation, and access to capabilities relevant to subsequent development.

The aggregate figures show that licensing had become a material source of revenue while Hengrui continued expanding its own research. Licensing revenue increased from RMB 2.70 billion in 2024 to RMB 3.39 billion in 2025, while total R&D investment rose from RMB 8.23 billion to RMB 8.72 billion (Jiangsu Hengrui Pharmaceuticals Co., Ltd. 2026). By the end of 2025, Hengrui had obtained approval for 24 new molecular entity drugs in China. It had more than 100 proprietary candidates in clinical development and over 400 clinical studies underway. Innovative drugs accounted for 58.34% of its drug-sales revenue (Jiangsu Hengrui Pharmaceuticals Co., Ltd. 2026). Licensing did not finance the entire research enterprise, but it had become a substantial additional source of revenue alongside domestic product sales.

Hengrui's experience shows how a firm can use the global licensing market to sustain a transition already underway. The company could activate this external alternative because its earlier generic business and fast-follow research had produced a pipeline that foreign partners considered

valuable. NVBP weakened the internal financing model that had supported this accumulation, while management remained uncertain that China's reimbursement system could immediately generate sufficient returns from innovative drugs. License-outs helped bridge the resulting interval by supplying current income, sharing development risk, validating Hengrui's assets, and connecting its researchers to foreign development capabilities. Territorial divisions also allowed Hengrui to retain and continue developing its domestic pipeline. External support did not create Hengrui's innovative capacity or pull the company out of China. It helped preserve and expand that capacity as the foundations of its old business model receded.

4.8 Discussion and Conclusion

Innovation poses a demanding institutional problem. Yet China's pharmaceutical industry sustained its move toward an innovation-driven model even as domestic cost-containment reform compressed the returns to its established business. This chapter explains how that transition remained possible. It shifts attention from whether supporting institutions exist to when they become usable. Domestic institutions are often precisely what reform seeks to improve. But reform can create a support gap when it erodes an old source of support before the institutions needed for a new model are ready. Actors must then decide whether they can continue investing through the interval. One possible response is to activate institutions outside the main domestic support structure. These institutions gain value because they operate independently of the reform's timetable.

China's pharmaceutical transition illustrates this temporal problem. Regulatory reforms beginning in 2015 expanded the state's capacity to evaluate novel drugs and brought Chinese technical standards into closer alignment with international practice. These changes made novel drug development more feasible, but they did not immediately create a domestic market that could finance it or reliably reward success. Public reimbursement remained constrained. Firms also faced uneven hospital access and often had to accept steep price reductions in exchange for coverage. NVBP then weakened the generic commercialization model on which much of the industry had relied. Novel drugs became more attractive by comparison, even as firms lost generic cash flows that had financed their emerging research programs. Reform increased the incentive to innovate while reducing firms' ability to pay for it.

The empirical evidence is consistent with this sequence. In the first analysis, firms whose pre-reform portfolios were more exposed to the product categories targeted by NVBP experienced larger post-2019 increases in CDE registration activity. Greater reform pressure was associated with stronger reorientation toward drug development. Sustaining that reorientation, however, de-

pended partly on firms' ability to draw on an external institution. Among firms with similar pre-transaction characteristics, those securing a first cross-border license-out subsequently recorded larger increases in domestic Phase I–III CDE activity than their matched controls.

Domestic institutional incompleteness continued to constrain China's pharmaceutical boom, but it did not halt the transition. Firms with internationally valuable assets could use the global licensing market to work around domestic limitations. External institutions supplied capital and overseas commercialization opportunities that remained scarce at home. Recognition by foreign partners also validated Chinese assets. These resources helped sustain an innovation transition already underway while the domestic system matured.

4.8.1 Why Hospitals and Pharmaceutical Firms Diverged

This argument also clarifies why pharmaceutical firms diverged from the hospitals examined in Chapter 3. Chapter 3 shows that anti-corruption reform weakened hospitals' informal operating capacity and worsened service-delivery outcomes. In both settings, the state weakened arrangements that had supplied organizations with revenue and operational flexibility before a complete replacement was available. What differed was actors' access to an institutional bridge outside the changing domestic system.

Hospitals had few such options. Most hospitals are public organizations governed within China's administrative system. Their physical and organizational assets were also tied to particular localities. They could not travel in the way that intellectual property in novel drugs could. Once reform removed informal fiscal and coordination mechanisms, hospitals remained dependent on a domestic system that had yet to provide a complete replacement.

Pharmaceutical firms held more portable assets. Novel drug candidates could be evaluated across jurisdictions, and their development rights could be transferred between firms. Those rights could also be divided by territory. A Chinese firm could license foreign development or commercialization rights while retaining domestic rights and continuing research at home. Regulatory alignment made Chinese evidence more legible to potential partners and overseas regulators. Licensing then converted that legibility into capital and access to foreign development capabilities.

This difference in asset portability helps explain why discipline before replacement produced different organizational responses. For hospitals, the withdrawal of established support generated strain without supplying the means to construct a new model. Pharmaceutical firms with portable assets could instead draw temporary support from external institutions, provided the state allowed

cross-border transactions. The relevant divide cuts across the public–private distinction. It separates activities bound to the domestic institutional environment from those able to draw value from another system without abandoning their domestic base.

The comparison also qualifies broad claims about state discipline. Removing rents or tightening cost controls does not automatically improve organizations, even when the old arrangements are inefficient. Outcomes depend partly on what actors can rely on during the transition. Chapter 3 shows that discipline without replacement can damage service delivery and encourage cost shifting. This chapter shows that an accessible external bridge can support reallocation toward a more productive model, even though this opportunity is selective. Reform may accelerate upgrading among capable firms while widening the gap between them and firms unable to externalize their assets.

More broadly, the comparison shows why analyses of institutional transition must look beyond replacement institutions created within the reforming state. The Chinese state improved its regulatory system and made it more interoperable with international practice. It also kept cross-border licensing channels open. Yet the state did not itself supply all the support that firms used during the transition. Foreign partners and capital markets provided financing and commercialization opportunities unavailable at home. State action shaped the interface through which firms reached these institutions, even though the institutions themselves remained outside the domestic system.

4.8.2 What This Means for China's Innovation Model

China's pharmaceutical innovation boom is real, but its institutional foundations require careful interpretation. Domestic reform and global markets each supplied part of what firms needed. The state improved drug regulation and made Chinese clinical evidence more portable while pushing firms away from the generic model. Global institutions helped firms finance and commercialize assets that the domestic market could not yet reward on comparable terms. China's pharmaceutical transition emerged from the interaction between domestic reform and external opportunity.

That interaction also makes the model fragile. Continued license-out activity requires foreign pharmaceutical companies to value Chinese assets and global capital to finance their development. Chinese clinical data must remain acceptable to overseas regulators, while domestic authorities must permit cross-border transfers of development rights. All of this presumes a geopolitical environment in which foreign firms remain willing and legally able to acquire Chinese-origin assets. If any of these conditions deteriorates, the external channel could narrow before domestic institutions are ready to replace it.

Externalized support cannot permanently substitute for domestic institution building. A bridge succeeds only if it leads to a more durable arrangement. A durable innovation system still requires predictable domestic reimbursement and financing capable of absorbing clinical-development risk. Novel products also need reliable access to hospitals and patients. If these institutions fail to mature, externalization may become a continuing dependence on foreign commercialization. Firms may also move more development activity and future returns abroad. If the external channel closes before a domestic replacement is ready, the support gap will reopen.

China's pharmaceutical innovation boom rests on a transitional arrangement, not a completed institutional model. Global licensing has bought capable firms time. The long-term outcome will depend on whether China uses that interval to build the domestic institutions that innovation still requires.

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