Regulatory Reliance, Foreign Drug Approvals and Healthcare Spending

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Abstract

An extensive literature examines how regulation affects market entry, but less is known about how reliance on foreign pharmaceutical assessments relates to domestic spending. We link a legal corpus covering 250 countries and areas to pharmaceutical imports and healthcare expenditure. A 94-country comparison separates foreign approval credentials from usable assessments. GDP-weighted comparisons across 62 treated jurisdictions associate a 2.25-fold difference in prior medicine-import dependence with a 2.46-percentage-point larger increase in government financing share. Household surveys provide new evidence of reduced medical borrowing and financial hardship in more import-dependent countries. We extend a model of regulatory assessment to incorporate public financing.

Keywords: Regulatory reliance; pharmaceutical regulation; legal texts; natural language processing; topic models; regulatory recognition; international diffusion; assessment reports; standardized cases; market entry.

JEL Classification: I18, L51, L65, K23, C38, F15.

1 Introduction

An extensive literature shows that legal rules shape the costs of entering markets and the incentives firms face when deciding where to operate (Djankov, La Porta, Lopez-de Silanes, and Shleifer, 2002; Kyle, 2007; Maini and Pammolli, 2023). In pharmaceutical markets, a medicine already authorized abroad may require another scientific assessment before it can be sold domestically. Regulatory reliance allows the domestic authority to use a trusted foreign authority's assessment when making its own authorization decision. The World Health Organization recommends this approach to reduce duplicated work, make better use of limited regulatory expertise, and facilitate timely access to safe and effective medicines (World Health Organization, 2021).

Achieving these benefits requires more than accepting that another country has approved the medicine. The domestic regulator may need the underlying scientific reports, permission to obtain confidential information, and confirmation that the application concerns the same product. National rules may also require further evidence relevant to local patients and treatment practices. These conditions determine whether foreign work can actually replace domestic assessment and how much additional review remains necessary. Understanding reliance therefore requires examining what information national rules allow regulators to use, alongside the foreign approvals they recognize.

The consequences for healthcare spending depend on what happens after authorization. Manufacturers must decide whether to supply the medicine, and governments and insurers must decide whether to cover treatment. If newly authorized medicines receive public coverage, government payments may increase; if households purchase them directly, household payments may increase instead. Who pays matters because public insurance can protect households from large medical bills (Finkelstein and McKnight, 2008) and affect pharmaceutical prices and use (Duggan and Scott Morton, 2010). Reliance may therefore improve the authorization process without producing a corresponding reduction in household payments. We examine whether documented reliance arrangements are associated with changes in pharmaceutical imports, household healthcare payments, and the share of healthcare expenditure financed by government. These outcomes separate changes in medicine purchases from changes in how the costs of care are shared.

In this paper, we examine how regulatory reliance relates to pharmaceutical imports and healthcare financing using an international legal corpus for 2000–2025 linked to annual trade and health-expenditure data. The corpus is indexed to 250 countries and areas and records the foreign approvals, assessment reports, sharing permissions and domestic checks specified by documented routes. In the primary difference-in-differences compar-

ison of 62 treated jurisdictions, a roughly 2.25-fold difference in prior medicine imports relative to GDP is associated with a 2.46-percentage-point larger increase in the government share of healthcare spending when countries are weighted by pre-reform real GDP. Capping GDP weights at the treated-sample 95th percentile gives 2.31 points. Restricting treatment to documented national routes, excluding WHO participation and shared European authorization as qualifying events, yields 23 treated jurisdictions and a stronger effect where the GDP-weighted coefficient is 4.50 percentage points, compared with 2.46 points in the broader sample. Separate expenditure comparisons associate national arrangements with 8.1% higher packaged-pharmaceutical import expenditure per person and 10.3% lower household out-of-pocket healthcare expenditure per person relative to comparison countries. We find that countries with greater prior medicine-import dependence experience larger increases in the government share of healthcare spending following reliance arrangements, while separate expenditure comparisons show higher medicine imports and lower household payments.

Following our main finding, we ask whether the financing association persists after accounting for economic conditions that may influence both regulatory choices and healthcare spending. We compare changes within countries before and after documented reliance arrangements, using countries with later-dated arrangements as the comparison group. In supplementary national-route regressions, greater prior medicine-import dependence remains associated with a larger increase in the government share of healthcare spending after accounting for changes in income, consumer prices and exchange rates. After accounting for changes in income, consumer prices and exchange rates, we continue to find that greater prior medicine-import dependence is associated with a larger increase in the government share of healthcare spending following reliance arrangements.

We continue to find new evidence of reduced household financial strain in more import-dependent countries using secondary survey data. In the pandemic-adjusted Global Findex comparison, a one-standard-deviation increase in prior medicine-import dependence is associated with a 5.23-percentage-point larger decline in medical borrowing following national reliance arrangements. In the separate WHO collaborative-registration comparison, controlling for prior external health financing gives exposure coefficients of -5.61 percentage points for financial hardship and -5.69 points for its impoverishing-spending component. These outcomes capture the financial pressure households face when paying for care and the survey findings support the interpretation of our main financing results by providing separate evidence that more import-dependent countries experience larger reductions in household financial strain following reliance arrangements.

We next adapt the market-size and profit-incentive framework of Acemoglu and Linn (2004) to medicines that already exist internationally. Manufacturers compare the expected return from domestic sales with the costs and delays of the available approval procedures. Foreign credentials, scientific reports and sharing permissions determine which procedures they can use, while purchases by governments, households and external programmes determine the commercial opportunity. Three propositions connect usable information to application value, purchasing opportunities to the composition of entry, and payer decisions to the government share of healthcare spending.

To examine these institutional distinctions, we follow the standardized-case approach of Djankov et al. (2002); Djankov, Hart, McLiesh, and Shleifer (2008). We apply the documented rules to the same hypothetical medicine in 94 countries, holding the manufacturer, product characteristics and application dossier constant. We then vary the availability of foreign assessment reports, sharing permissions and prior approvals to establish how each condition changes the applicant's available approval procedures. This comparison identifies differences arising from national rules while accounting for alternative routes. The text analysis complements this comparison by identifying how legal documents address access to scientific reports, recognition of foreign approvals and the use of foreign regulatory information.

Having examined how national rules affect the available approval procedures, we return to the expenditure results to ask why household payments are lower following reliance arrangements. Lower household payments could reflect either lower overall healthcare spending or a smaller share paid directly by households. On identical observations and weights, the 10.3% lower household-spending estimate corresponds to 1.9% higher total healthcare expenditure and an 11.9% decline in the household-financed fraction. The lower household-spending estimate therefore mainly reflects a change in who pays for care, rather than a reduction in total spending.

We next examine whether government spending contributes to this change in financing. In the GDP-weighted 62-jurisdiction comparison, the spending estimates imply 8.1% higher government healthcare expenditure per person, 2.7% higher total expenditure and 2.5% lower household expenditure for the headline import-exposure contrast. Although these individual spending estimates are imprecise, their pattern helps explain the larger government financing share: government expenditure rises faster than total healthcare expenditure. A possible mechanism is that reliance facilitates authorization and governments subsequently cover some of the available treatments, increasing the proportion of care financed through public budgets. The results are consistent with this mechanism, but do not directly establish that reliance expanded public coverage.

In further robustness tests, we also examine whether the national-route financing association persists after accounting for other economic and pandemic-related changes, and whether it is driven by any single country. The coefficient remains positive at 3.64 percentage points after controlling for changes in income, prices and exchange rates, 2.95 points with mortality and containment controls, and 2.99 points when total-import exposure is included. Excluding each country in turn gives coefficients between 2.61 and 4.35 points. These checks show that the positive association persists under the additional controls and does not depend on any single country.

This paper makes three contributions. First, we extend comparative research on legal institutions to the international allocation of pharmaceutical assessment. Djankov et al. (2002), Djankov, La Porta, Lopez-de Silanes, and Shleifer (2003) and Djankov et al. (2008) compare requirements for a standardized business, dispute or insolvent firm; La Porta, Lopez-de Silanes, and Shleifer (2006) separate mechanisms within securities regulation; and Bosio, Djankov, Glaeser, and Shleifer (2020) distinguish procurement rules from practice and outcomes. We combine original legal wording, historical coding and a common pharmaceutical applicant. Text analysis (Gentzkow, Kelly, and Taddy, 2019) describes recurring provisions, while the fixed-product comparison establishes their implications for a specified application. This makes report access and transmission conditions observable components of regulatory integration.

Second, we connect pharmaceutical entry costs with the reuse of information across jurisdictions. Research on price controls and international reference pricing emphasizes manufacturers' incentives to enter (Kyle, 2007; Maini and Pammolli, 2023), while Wang, Li, and Anupindi (2023) examine regulatory review as a barrier to generic competition. Information also changes behavior: Krieger (2021) shows that firms learn from competitors' research failures, and Lee, Lee, Shin, and Krishnan (2021) links mandated information disclosure to shortage recovery. We apply these insights to a different setting, examining how domestic authorities use scientific assessments completed by foreign regulators to support domestic drug approval.

Third, we contribute to the literature on how healthcare costs are shared. Yapar, Chick, and Gans (2025) study how evidence and negotiations affect reimbursement, while Adida (2024) shows that pricing policies can benefit manufacturers without equally benefiting patients and payers. Changes in drug prices also need not translate directly into changes in spending (Feng and Maini, 2024). We extend this research to regulatory reliance by examining spending on imported medicines, household out-of-pocket payments and the government share of healthcare expenditure. The primary expanded comparison covers 62 treated jurisdictions and links greater prior medicine-import dependence to a larger gov-

ernment financing share; the secondary 23-jurisdiction national-route comparison gives a stronger association.

The remainder of the paper is organized as follows. Section 2 presents the institutional details and the model's key propositions. Section 3 describes the data and methodology. Section 4 reports the financial, textual and standardized-application findings, and Section 5 concludes. The full model and proofs appear in Appendix A.

2 Institutional details and hypotheses

2.1 Pharmaceutical law, market access and healthcare financing

Drug approval allows a medicine to be marketed, but manufacturers still decide whether to supply it and payers decide whether to cover treatment. Research examines each of these decisions. We draw on this literature to explain why reusing foreign assessments may reduce approval costs without necessarily lowering household payments.

Approval rules balance the benefits of additional evidence against the costs of delaying treatment. Peltzman (1973) argues that the 1962 US drug amendments reduced innovation and that the resulting losses exceeded the benefits from excluding ineffective medicines. Henry and Ottaviani (2019) show how control over research and approval affects the efficiency of evidence gathering. Cohen, Gurun, and Li (2021) find that approvals cluster around informal calendar deadlines and that drugs approved before those deadlines receive more subsequent adverse-event reports. These studies show why the organization of review matters alongside the evidence required.

Stronger evidence requirements can also benefit consumers despite higher prices and fewer products. Studying bioequivalence regulation in Chile, Atal, Cuesta, and Sæthre (2026) estimate an 18% reduction in the number of drugs and a 13% increase in average paid prices. Their model nevertheless finds higher consumer welfare because certification reduced uncertainty about generic quality. For reliance, the question is therefore which assessment tasks foreign evidence can replace while preserving checks relevant to domestic patients.

Patent protection affects the competition that follows approval. Chaudhuri, Goldberg, and Jia (2006) estimate substantial consumer losses from pharmaceutical product patents in India under a counterfactual withdrawal of domestic quinolones. Studying India's subsequent patent reform, Duggan, Garthwaite, and Goyal (2016) find average price increases of 3–6% following patent grants, with little change in quantities or firm numbers. The

studies examine different products and policy comparisons, but both show why the consequences of legal reform depend on what happens to competing suppliers.

Expected sales also shape drug development. Acemoglu and Linn (2004) find that larger potential markets encourage the development of new drugs, while Finkelstein (2004) finds more vaccine trials following policies that increased expected returns. Budish, Roin, and Williams (2015) show that private cancer research favors projects with shorter development periods, consistent with short-termism and fixed patent terms. Payer decisions matter as well: Agha, Kim, and Li (2022) find reduced investment in therapeutic classes more exposed to pharmacy benefit managers' exclusions of newly approved drugs. Lower assessment costs therefore operate alongside expected demand, patent protection and reimbursement.

For an existing medicine, manufacturers must also choose where and when to launch. Kyle (2007) links price controls to international entry strategies. Cockburn, Lanjouw, and Schankerman (2016) find that price regulation delays launches, whereas longer and broader patent protection accelerates them. Maini and Pammolli (2023) show that external reference pricing can encourage manufacturers to delay entry into lower-income countries because prices there affect revenues elsewhere. These findings explain why an easier authorization procedure may encourage an application without ensuring commercial supply.

Rules governing prescribing and payment affect spending after launch. In France, Tunçel (2025) estimate that banning off-label prescribing would increase treatment expenditure without improving health outcomes, with further increases when negotiated prices adjust. Authorization therefore leaves consequential decisions about how medicines are used and what payers will pay.

Insurance can change both treatment purchases and the amount patients pay directly. Duggan and Scott Morton (2010) find that Medicare Part D lowered prices for previously uninsured beneficiaries and increased prescription-drug use, with larger relative price declines among drugs facing substantial therapeutic competition. Einav, Finkelstein, and Schrimpf (2015) show that beneficiaries respond to cost-sharing incentives in Part D contracts. These findings motivate examining household payments, total expenditure and financing shares separately. Household payments can fall even when total spending rises.

Different forms of regulatory cooperation may also have different effects. Maggi and Ossa (2023) show that producer interests and lobbying can shape regulatory agreements and, under some conditions, produce excessive deregulation. Although their model does not study pharmaceutical reliance specifically, it cautions against treating all cooperation as equivalent. National reliance routes, shared authorization systems and product-specific

programmes may cover different medicines and change different decisions.

We therefore examine what reliance changes in the domestic approval process before assessing its relationship with spending. Our legal comparison separates foreign approval credentials from access to scientific reports and permission to share them. Our economic analysis examines pharmaceutical imports, household payments and government financing shares. This approach connects the approval process to the entry and payment decisions studied in the literature without treating an available legal route as evidence of commercial launch or public coverage. We begin by defining reliance and identifying which decisions remain domestic.

2.2 What constitutes a reliance arrangement?

A medicine approved in one country may require a further regulatory review before it can be marketed elsewhere. Repeated assessment places demands on regulators and manufacturers, even when the underlying scientific evidence is substantially the same. Regulatory reliance allows a domestic authority to use another authority's assessment in reaching its own decision. Its purpose is to reduce unnecessary duplication and make better use of regulatory resources, while preserving domestic responsibility for the authorization. An international survey of regulatory authorities documents the use of reliance across different regulatory systems, including well-resourced agencies (Doerr, Valentin, Nakashima, Orphanos, Santos, Balkamos, and Saint-Raymond, 2021).

Reliance encompasses several approaches that differ in how much assessment the receiving authority undertakes. An (1) abridged review uses foreign assessment findings while retaining selected domestic evaluation. A (2) verification procedure concentrates on whether the submitted medicine corresponds to the previously approved product and satisfies the route's conditions. (3) Recognition gives a foreign regulatory decision formal effect under the receiving jurisdiction's legal provisions, without an additional scientific assessment. WHO's guidance places these approaches within a broader framework in which the extent of reliance depends on the product, the available evidence and the domestic regulatory setting (World Health Organization, 2021). The amount and type of work retained domestically therefore matter alongside the name assigned to the procedure.

Access to the foreign assessment is a practical condition for many reliance routes. An approval certificate establishes that an authority authorized a product, but may provide little explanation of how it evaluated the evidence. The underlying assessment reports can contain the analysis needed to identify unresolved concerns and determine which questions require further review. In a study informing South Africa's abridged-review frame-

work, Keyter, Salek, McAuslane, Banoo, Azatyan, and Walker (2020) document requirements for matching applications and unredacted assessment reports; workshop participants also identified limitations in publicly available, redacted reports. More recently, Poulard, Ausborn, Allchurch, Palmi, Ganan, Joos, Deavin, Beauchesne, Shah, Krishnan, and Askri (2025) describe substantial variation in the documents requested by authorities relying on European assessments. Where confidential material is needed, access may depend on manufacturer consent or arrangements governing exchanges between regulators (World Health Organization, 2021). Recognizing a foreign authority and obtaining its scientific work are consequently separate institutional conditions.

The organization of cooperation also differs. Unilateral reliance allows an authority to use another's work without a reciprocal commitment, whereas joint review involves authorities sharing assessment activities (Doerr et al., 2021; World Health Organization, 2021). European arrangements illustrate a further distinction. Under mutual recognition, an existing national marketing authorization can be recognized in other participating countries. Under the centralized procedure, a European Commission authorization follows a common scientific assessment and is valid throughout the European Union (European Medicines Agency, 2024). These arrangements differ in their legal basis and territorial effect, even though each reduces the need for separate national assessment.

The scope of reliance varies across arrangements. Some cover particular types of medicines, while others apply to specific tasks, such as manufacturing inspections or changes to an already approved product (World Health Organization, 2021). Accepting a foreign inspection therefore does not necessarily mean accepting the foreign decision to authorize the medicine. Even when a regulator uses a foreign assessment, it may still examine whether the findings apply to local patients and treatment practices. Differences in population characteristics, disease patterns and clinical practice can justify additional domestic review (Mukonzo, Ndagije, Sabblah, Mathenge, Price, and Grasela, 2024).

2.3 Economic tensions in regulatory reliance

Regulatory reliance can reduce the work required to approve a medicine, but its economic benefits depend on what happens after that work is saved. A regulator must decide which foreign findings it can use and which questions require further assessment. A manufacturer must decide whether entering the domestic market is commercially worthwhile. Governments, insurers and patients then determine how treatment is financed. These decisions create three potential gaps between regulatory cooperation and its expected benefits.

The first concerns the balance between avoiding repeated work and addressing

domestic needs. Reassessing evidence already examined abroad consumes time and resources. However, the foreign review may concern a different formulation, manufacturing process or intended use, and its conclusions may require reconsideration where patient populations or clinical practices differ. Studies of abridged review document both product-matching requirements and continued assessment of locally relevant clinical factors (Keyter et al., 2020; Mukonzo et al., 2024). Requiring more domestic evidence can address these concerns, but also reduces the time and cost savings available through reliance. The economic question is which additional checks provide enough useful information to justify their cost.

The second concerns the manufacturer's decision to enter. A less costly application can make a previously unprofitable market worth serving. Yet regulatory costs are only one part of that calculation: expected sales, competition and domestic pricing policies also affect the return to entry (Kyle, 2007; Maini and Pammolli, 2023). Moreover, saving a fixed application cost does not necessarily change the most profitable selling price once the firm enters. Reliance can therefore encourage applications without producing a corresponding reduction in medicine prices. Authorization, reimbursement and commercial launch remain separate decisions, so an available regulatory shortcut does not guarantee that a medicine will reach patients.

The third concerns who benefits from lower regulatory costs. A regulator may use the saved staff time for other applications or safety monitoring. A manufacturer may retain its application-cost savings. Patients benefit financially only if a further change reduces what they pay, such as lower transaction prices or greater coverage by government or insurance. Evidence of reduced assessment effort and cost (Danks, Semete-Makokotlela, Gouws, Otwombe, Walker, and Salek, 2025) therefore concerns an earlier step than evidence of lower household payments. Section 2.4 examines how a wider treatment portfolio can increase the value of public coverage, subject to the cost and availability of public financing.

We examine spending on imported medicines and the healthcare costs paid directly by households. These measures capture different possible consequences of reliance. Easier approval may encourage additional medicine purchases, while changes in prices or public coverage may affect household payments. However, spending alone cannot distinguish these explanations. We therefore use these outcomes to examine changes in purchases and payments, without treating them as direct measures of medicine prices or patient access.

2.4 Theoretical framework and hypotheses

Following the market-size logic of Acemoglu and Linn (2004), we start with the expected return to supplying a pharmaceutical product. Their framework links profitable purchasing opportunities to innovation. We condition on medicines that already exist internationally and model the decision to seek domestic authorization. Our adaptation introduces national approval procedures and separates purchases financed by domestic government, households, external programmes and other payers. Appendix A provides the assumptions and proofs.

The supplier's decision. For medicine i and destination j, let $\Pi_{ij} \geq 0$ be its expected operating value conditional on authorization. This value reflects prices, treatment purchases, supply costs and international pricing incentives. National rules determine a set of available procedures, $\mathcal{P}_{ij}(A, R, C)$, given foreign approvals A, assessment reports R and sharing permissions C. The value of applying is

$$V_{ij} = \max\left\{0, \max_{p \in \mathcal{P}_{ij}(A,R,C)} \left[a_{ijp} e^{-\rho d_{ijp}} \Pi_{ij} - F_{ijp}\right]\right\}, \tag{2.1}$$

where a_{ijp} is the authorization probability, d_{ijp} the delay before returns begin, $\rho > 0$ the discount rate, and F_{ijp} the private application and documentary cost. A firm applies when an available procedure has positive net value. This separates the authorization decision from the reimbursement and pricing decisions determining subsequent purchasing opportunities (Henry and Ottaviani, 2019; McClellan, 2022; Yapar, Chick, and Gans, 2025).

Usable information and the choice of procedure. A foreign approval is a credential establishing procedural eligibility. Its underlying report supplies scientific information, and a lawful transmission channel determines access to that information. Domestic expertise $h_j > 0$ governs the usable part of an accessible report:

$$\text{usable foreign precision} = \phi(h_j)R, \qquad \phi(h_j) = \frac{h_j}{h_j + \kappa}, \quad \kappa > 0. \tag{2.2}$$

This interpretation technology draws on Cohen and Levinthal (1990); the assessment benchmark builds on the value of information in Blackwell (1953); Liang, Mu, and Syrgkanis (2022). In the appendix's quadratic assessment problem, foreign information replaces repeated domestic scientific work while preserving the accuracy attained in the interior. Once repeated work reaches zero, further information improves accuracy.

Proposition 2.1 (Usable information, procedures and application value)**.** *Holding the assessment mandate fixed, additional usable foreign information weakly reduces repeated domestic assessment. If a qualifying approval or sharing permission expands the available procedure set, and existing options retain their authorization probabilities with weakly lower private costs or delays, application value weakly increases. The increase is strict when a newly available or improved procedure raises the best attainable net return above its previous value.*

The proposition connects the common-medicine exercise to a firm's choice set. Complete reports, a second approval and permission to share a report can unlock different procedures. A remaining alternative can preserve entry opportunities when one shortcut is unavailable. A reduction in regulator effort reaches the firm's decision through application requirements, fees or waiting time; these are separate objects in equation (2.1).

Purchasing opportunities and product composition. Expected operating returns depend on purchases by each financing source. We distinguish $k = F$, a first ingredient-family opportunity, from $k = A$, an additional option within an existing family. Given authorization probability a_{jk}, potential foreign-product pool x_{jk}, and an applicant-specific cost with cumulative distribution Ψ_k, expected authorizations are

$$N_{jk} = a_{jk} x_{jk} \Psi_k(W_{jk}), \qquad W_{jk} = \max_{p \in \mathcal{P}_{jk}} \left\{ a_{jk} e^{-\rho d_{jkp}} \Pi_{jk} - f_{jkp} \right\}. \tag{2.3}$$

Here W_{jk} is expected return before the applicant-specific cost. The purchasing opportunities within Π_{jk} can differ across governments, households and external programmes. This extends the profit-incentive argument to international diffusion and the distribution of payment across purchasers (Acemoglu and Linn, 2004; Duggan and Scott Morton, 2010).

Proposition 2.2 (Profitable demand and the composition of entry)**.** *For fixed authorization probabilities and other market conditions, higher expected operating returns or lower private application costs weakly expand profitable applications and expected authorizations. The response can differ between first ingredient families and additional options. With uniformly distributed applicant costs and an interior cutoff, a cost reduction $\delta_{jk} r_j$ gives $\partial N_{jk} / \partial r_j = a_{jk} x_{jk} \delta_{jk} / \bar{c}_{jk}$, where $\bar{c}_{jk}$ is the upper bound of the cost distribution.*

A larger profitable foreign-product pool therefore permits a larger response to a usable route. Prior medicine-import dependence motivates this heterogeneity comparison. The distinction between first families and additional options also organizes the registration

evidence: an additional authorization can represent a new strength, supplier or presentation of an already represented ingredient. Authorization and the subsequent treatment purchases remain separate decisions.

Public coverage and financing incidence. The payer chooses coverage and purchases subject to a budget, valuing financial protection and treatment benefits. Its optimal response depends on medical value, existing alternatives, external support and the fiscal cost of public funding. The appendix derives this choice from a concave payer problem. Let B_{jk} denote additional treatment expenditure, g_{jk} its domestic-government-financed fraction, and τ_j an existing treatment bill transferred from households to public coverage. The government share is

$$S_{Gj} = \frac{G_{j0} + \sum_k g_{jk} B_{jk} + \tau_j}{T_{j0} + \sum_k B_{jk}}. \tag{2.4}$$

Proposition 2.3 (The marginal purchaser determines the financing response)**.** *Along a differentiable response to reliance, holding spending elsewhere and the fractions g_{jk} fixed,*

$$\frac{dS_{Gj}}{dr_j} = \frac{\tau_j' + \sum_k (g_{jk} - S_{Gj}) B_{jk}'}{T_j}. \tag{2.5}$$

The government share rises when the expansion of public coverage and government-financed treatment exceeds the expansion financed elsewhere. It can fall when additional treatment is financed disproportionately by external or private purchasers.

This proposition connects the financing comparisons to the marginal purchaser. Public coverage can shift an existing bill toward government without increasing total expenditure. Additional government-financed treatment can raise its share, while externally financed treatment can lower the domestic-government share. At fixed household financing fractions h_{jk}, household expenditure falls when $\tau_j' > \sum_k h_{jk} B_{jk}'$. The model thus links legal options to profitable applications, and purchasing decisions to the allocation of healthcare payments.

2.5 Model implications and empirical analysis

The model extended from Acemoglu and Linn (2004) explains why easier authorization need not reduce household payments. Usable foreign evidence can improve the procedures available to manufacturers, but firms apply only when expected sales justify the remaining costs. Governments then decide whether to finance treatment. The financing response therefore depends on both the commercial opportunities created by reliance and the purchasing decisions that follow. We examine these steps separately.

First, Proposition 2.1 directs attention to what manufacturers need to use a reliance procedure. A recognized foreign approval may be insufficient when the underlying report or permission to share it is unavailable. We therefore apply national rules to the same hypothetical medicine and vary its approvals, reports and sharing permissions. This exercise establishes which conditions change the available procedures and whether another route remains available.

Second, Proposition 2.2 suggests that lower application costs can encourage authorization where profitable purchasing opportunities exist. We examine pharmaceutical import expenditure and ask whether the financing response differs with prior medicine-import dependence. Registration records also allow us to compare first-recorded ingredient families with additional product options, without treating every registration as a new therapeutic introduction.

Third, Proposition 2.3 explains why additional authorizations need not increase the government financing share. That share rises when public coverage expands or additional treatment is financed more heavily by government than existing care. It can fall when purchases are financed mainly by households or external programmes. We therefore examine government, household and total expenditure together, and use survey measures of borrowing and financial hardship to assess whether the spending patterns coincide with reduced household financial strain.

3 Data and methodology

3.1 Primary data: the regulatory-text corpus

Our primary data are a legal corpus indexed to 250 countries and areas for 2000–2025. We construct it from publicly available statutes, implementing regulations and official guidance, retaining the original wording, source address and document version. The collection contains 444 country-specific passages from 134 jurisdictions and nine passages on shared procedures. We use 89 selected national-pathway texts to code legal requirements, 65 texts for language analysis and 94 country cases for the standardized-medicine comparison (Table 1).

We record accepted foreign authorities, eligible products, required reports, sharing permissions and the assessment retained domestically. National routes, shared authorization, restricted procedures and cooperation frameworks remain separate categories. We distinguish operative dates from enactment, observed operation and amendments, carrying provisions forward until an identified change. The dated record contains 49 juris-

dictions by 2025, including 41 national routes. We corroborate pathway coding against Poulard et al. (2025) and use the WHO framework to distinguish recognition and abridged assessment (World Health Organization, 2021). Online Appendix reports historical coverage and date conventions.

Following Gentzkow, Kelly, and Taddy (2019), we compare selected texts after removing country names and common boilerplate, combining grammatical variants and harmonizing spelling. Negations and terms indicating requirements or discretion are retained. TF–IDF and cosine similarity measure shared vocabulary; latent Dirichlet allocation (LDA) identifies recurring themes. The 65-text language sample contains 52 English sources and 13 checked translations. Online Appendix reports model selection and sensitivity checks.

3.2 Secondary data: economic and household surveys

We link the legal record to UN Comtrade pharmaceutical imports and World Bank/WHO healthcare expenditure (United Nations Statistics Division, 2026; World Bank, 2026). Both sources contain observations for 193 jurisdictions. Annual source data cover 2000–2024; the primary financing comparisons use complete event windows with outcomes through 2023. Available 1995–1999 observations establish pre-event exposure for early arrangements. Packaged-medicine imports use HS3004, measured per person and relative to GDP, total imports or machinery imports. Expenditure combines prices, quantities and product composition. We use healthcare data to examine household, government and total spending, together with the shares financed by households and government. Additional specifications adjust spending for differences in purchasing power and inflation.

The household surveys provide separate measures of financial strain. Global Findex records medical borrowing in 2014, 2017, 2021 and 2024 (World Bank, 2025); Afrobarometer records going without medicines or treatment and selected facility problems (Afrobarometer, 2026). HEFPI and WHO report catastrophic spending, financial hardship and impoverishing expenditure from observed household surveys (World Bank, 2022; World Health Organization, 2025). We analyze sources separately, retaining their original denominators and the distinct HEFPI and WHO definitions. EHIS, EU-SILC and Australian and New Zealand surveys provide additional affordability histories. Table 2, Panel C summarizes coverage.

TABLE 1
Data, estimation samples and standardized applications

Panel A: Legal corpus and analytical samples

Sample	Count	Use in the study
Countries and areas searched	250	Geographic coverage of the collection.
Jurisdictions with reviewed national passages	134	Coverage of country-specific documentary evidence.
Country-specific passages	444	Original legal wording used to identify national requirements.
Shared-procedure passages	9	Documentation of shared authorization arrangements.
National-pathway texts	89	Coding of legal requirements and domestic decision powers.
Texts used in language analysis	65	Comparison of vocabulary and recurring themes.
Countries in the hypothetical-medicine comparison	94	Application of documented requirements to a common product.

Panel B: Economic estimation samples

Estimation sample	Treated	All countries
Primary expanded financing comparison	62	67
Secondary national-route comparison	23	30
Supplementary national-route controls	17	33
Medicine-import expenditure comparison	20	35
Household-expenditure comparison	20	37
Findex borrowing, pandemic-adjusted	10	16
WHO financial-protection comparison	12	22

Panel C: Five applications for the same medicine

Case	Prior approvals	Reports and permissions
A	FDA + EC	Public summaries available; complete assessment reports unavailable to the domestic regulator.
B	FDA + EC	Complete assessment reports and all required sharing permissions available.
C	FDA + EC	Complete reports obtainable; applicant or manufacturer consent unavailable where required.
D	FDA + EC	Complete reports obtainable; foreign-regulator sharing permission unavailable where required.
E	FDA only	Complete FDA reports and all required permissions available; European approval removed.

This table shows the legal corpus, economic estimation samples and standardized-medicine applications. Panel A reports the overlapping analytical samples drawn from the same collection; the language-analysis sample comprises 52 English sources and 13 checked translations. Panel B reports treated and total country counts for each economic outcome. Countries may enter the comparison pool before their own documented date; outcome availability and the required history determine sample membership. Panel C defines five applications that vary prior approvals, complete reports and sharing permissions while holding the product, applicant, manufacturer and company dossier constant. FDA denotes the U.S. Food and Drug Administration; EC denotes the European Commission.

TABLE 2

Summary statistics and the economic content of dated arrangements

Panel A: Main expanded sample before reliance

	Treated jurisdictions			Comparison jurisdictions		
Characteristic	Mean	Standard deviation	Observations	Mean	Standard deviation	Observations
Household spending per person (US$)	266.9	294.0	62	306.3	309.0	262
Real GDP per person (constant US$)	15841.8	18175.3	62	16373.3	16748.6	262
Government share of health spending (%)	53.7	17.5	62	49.1	14.4	262
Medicine imports/GDP (%)	0.4	0.3	61	0.6	0.5	261

Panel B: Economic content of the 41 dated national-route records

Documented change	Records	Date verified
New access	27	16
Expanded eligibility	3	2
Tighter eligibility	1	0
Procedural amendment	3	2
Unresolved	7	1

Panel C: Secondary household-survey sources

Source	Observed coverage	Household measures
Global Findex	2014, 2017, 2021, 2024	Borrowing for medical expenses; national and demographic-group rates.
Afrobarometer	Rounds 2–10	Going without medicines/treatment; facility contact, medicine shortages, personnel and waiting.
World Bank HEFPI	1985–2019	Catastrophic and impoverishing spending; observed household-budget survey estimates.
WHO financial protection	1985–2024	Financial hardship and its components; 2025 SDG 3.8.2 definition.
EHIS / EU-SILC	2014/2019; 2008–2025	Prescribed-medicine affordability and unmet care due to cost.
Australia ABS / New Zealand Health Survey	2011/12–2024/25	Prescription-cost barriers, service access and insurance; descriptive histories.

This table shows pre-reform country characteristics, the economic content of dated arrangements and the secondary household surveys. Panel A reports pre-event means and standard deviations using the same GDP weights as the primary 62-jurisdiction financing comparison. The 324 country–event observations comprise 62 treated and 262 comparison observations across 67 countries; comparison countries may recur across event groups. Variables are measured in year $g-1$, and observation counts reflect variable availability. Panel B classifies the 41 dated national-route records by the change documented in the selected instrument and separately reports calendar verification. Panel C reports observed source coverage; analyses use years 2000 onward where supported. Findex measures adults 15+, Afrobarometer measures adult respondents and their families, and financial-protection files retain their source populations. Australian prescription affordability is conditional on needing prescriptions; the New Zealand measure covers all adults. Survey sources are analyzed separately.

3.3 Medicine-route analysis

Following the standardized-applicant approach of Djankov et al. (2002, 2008), we compare requirements for the same medicine in 94 countries. The applicant seeks ordinary authorization for an originator small-molecule medicine for adults. We hold the manufacturer, applicant, U.S. manufacturing facility, formulation, strength and indication constant, with a complete common technical document dossier and the relevant data rights. The baseline has FDA and European Commission approvals granted after standalone assessments 18 months before domestic application, with the medicine already marketed in both jurisdictions.

We code 23 components covering eligibility, prior approvals, product matching, reports, permissions, local evidence and domestic assessment. The five cases in Table 1, Panel C vary complete foreign assessment reports, permission to transmit them and European approval while keeping the company dossier complete. Comparing Cases B and A isolates access to complete reports; B versus C or D isolates the relevant permission; B versus E removes European approval. We apply each requirement within its stated scope, retaining alternative routes and distinguishing agency approvals from approval in multiple countries. Online Appendix reports the country-level applications.

3.4 Empirical design and comparison methods

We compare countries with a documented arrangement in year g against countries whose qualifying arrangements occur later. For annual outcomes, the change is

$$\Delta Y_{cg} = \frac{1}{3}\sum_{h=1}^{3} Y_{c,g+h} - Y_{c,g-1}, \tag{3.1}$$

excluding the event year. Expenditure enters in logs and financing shares in percentage points. Comparison countries have dates after $g + 3$, with at least two complete comparisons in each date group. Following Callaway and Sant'Anna (2021), countries serve as controls only before their own qualifying event.

Our average comparison is

$$\Delta Y_{cg} = \alpha_g + \beta T_{cg} + \varepsilon_{cg}, \tag{3.2}$$

where T_{cg} identifies the dated arrangement and α_g absorbs the common change within its comparison window. The primary financing comparison uses pre-reform real GDP weights, calculated as real GDP per person multiplied by population in year $g - 1$. Com-

parison weight mass is normalized to treated weight mass within each event group. A sensitivity comparison caps GDP weights at the treated-sample 95th percentile. Secondary equal-country-weighted comparisons assign unit weight to treated countries and normalize comparison weights within each group. We examine earlier changes and alternative dates to assess the parallel-trends assumption.

To study differences across financing environments, we estimate

$$\Delta Y_{cg} = \alpha_g + \beta T_{cg} + \theta(T_{cg} Z_{cg}) + \pi Z_{cg} + X'_{cg}\delta + u_{cg}, \tag{3.3}$$

where Z_{cg} is measured over $g-4$–$g-2$. Prior medicine-import exposure is the mean log ratio of HS3004 imports to GDP, standardized on the original sample; one unit represents approximately a 2.25-fold difference. Other moderators are prior household financing and income, expressed in standard-deviation units. Motivated by the pre-reform insurance comparisons of Finkelstein (2007), we retain each characteristic's main effect and examine moderators jointly. Baseline controls include prior income, the pre-event outcome and its earlier trend. Separate comparisons add demographic, fiscal, trade, pandemic and macroeconomic covariates.

For surveys, ΔY is the observed change within the same pre/post survey-wave pair and reform-year group. Pre-survey fieldwork ends before the earliest documented date; post-survey recall starts after the latest date and the implementation lag. Findex uses national arrangements; WHO financial protection uses participation in collaborative registration for prequalified medicines. Controls include prior income and the baseline outcome. The pandemic adjustment interacts prior public financing with the change in recall-period overlap with 2020–2021; the WHO adjustment adds prior external health financing. Survey-pair fixed effects absorb shared changes. The financing bridge uses identical observations, controls and weights across Findex borrowing and national spending outcomes.

We screen the full jurisdiction inventory, with inclusion determined by the documented legal history and available outcome data. Our main financing comparison includes 62 treated jurisdictions, combining national reliance routes, shared European authorization and WHO participation. We then restrict treatment to documented national routes in 23 jurisdictions. A separate 2023 cross-section links national legal profiles to healthcare financing, controlling for income, population, age composition and region. We account for correlations among observations from the same country when calculating standard errors. Financing and survey comparisons use CR2/Satterthwaite corrections to adjust confidence intervals and significance tests for the limited number of countries

(Pustejovsky and Tipton, 2018), alongside wild cluster bootstrap checks at the country level (MacKinnon and Webb, 2018). The Online Appendix provides further details on timing, comparison groups and statistical methods, together with a table of variable definitions and construction rules.

4 Findings

We start our empirical analysis by asking whether documented reliance arrangements are associated with changes in who pays for healthcare, particularly where countries depend more on imported medicines. After establishing the public-financing response, we use the corpus and a common medicine to examine the rules behind reliance. We then study the payer mix, household financial strain and alternative explanations, before examining the proposed public-financing mechanism. Figure 1 sets out these connected questions.

4.1 Reliance arrangements and public financing

We begin by asking whether reliance arrangements are followed by larger increases in government financing shares in countries with greater prior dependence on imported medicines. Our main comparison combines national routes, WHO collaborative-registration participation and shared European authorization, covering 62 treated jurisdictions and 67 countries. Using pre-reform real GDP weights, an approximately 2.25-fold difference in prior medicine imports relative to GDP is associated with a 2.46-percentage-point larger increase in the government share of healthcare spending, with a 95% confidence interval of [0.17, 4.75]. Capping GDP weights at the treated-sample 95th percentile gives 2.31 points [0.50, 4.13] (Table 3, Panel A). Thus, more import-dependent countries show larger increases in government financing shares in the main GDP-weighted comparison.

We next restrict treatment to documented national routes, excluding WHO participation and shared European authorization as qualifying events. In this 23-treated-jurisdiction sample, the GDP-weighted coefficient is 4.50 percentage points [1.44, 7.56], compared with 2.46 points in the broader sample. Equal country weights give 3.21 points in the pooled specification and 4.70 points when treatment and exposure terms vary across reform-date groups (Table 3, Panel B; Figure 2). The positive association therefore also appears when treatment is defined by national routes and when countries receive equal weight.

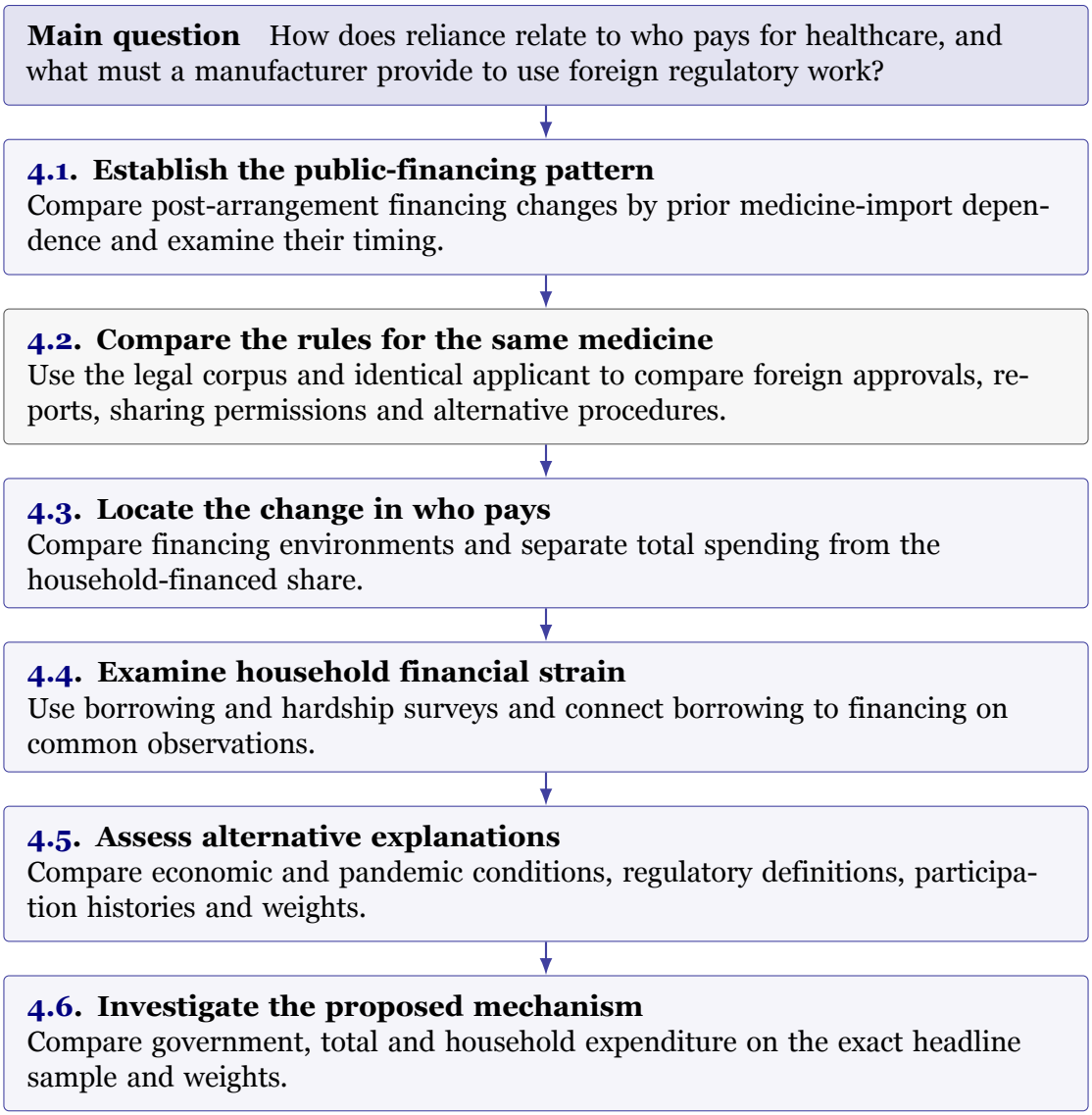


Figure 1: How the findings address the research question

This figure shows the sequence of questions addressed in the Findings section. The analysis moves from public financing to the legal requirements facing an identical medicine, then examines the payer mix, household financial strain and alternative explanations. The final comparison investigates the proposed mechanism through government, total and household expenditure on the headline sample. Arrows indicate the order of analysis.

We then examine when the financing difference appears in the primary expanded sample. The GDP-weighted coefficients for the first three full post-event years are 1.72, 2.71 and 2.95 percentage points; capped GDP weights give 1.58, 2.68 and 2.69 points (Figure 2, Panel B). The point estimates rise after the first year under both weighting schemes. For comparison, the original broader sample of 48 treated jurisdictions, using equal country weights and outcomes through 2020, gives a three-year coefficient close to zero. The financing association therefore varies with the sample, weighting and observation period. To understand what the underlying arrangements change in the approval process, we next apply the documented rules to the same hypothetical medicine.

TABLE 3
Public-financing responses in expanded reliance samples

Panel A: Primary expanded and secondary national-route comparisons

Variables	(1)	(2)	(3)
Treated-jurisdiction sample	62	62	23
Weights	GDP	Capped GDP	GDP
Reliance × prior import exposure	2.460**	2.315**	4.499**
	[0.774]	[0.703]	[0.995]
Documented reliance arrangement	1.878*	1.894**	2.343
	[0.796]	[0.694]	[1.708]
Prior import exposure	-1.492	-1.458*	-2.204**
	[0.949]	[0.644]	[0.831]
Pre-reform log real GDP per person	1.410**	1.377**	0.229
	[0.428]	[0.395]	[0.956]
Pre-reform government-financing share	-0.106**	-0.105**	-0.018
	[0.035]	[0.033]	[0.079]
Earlier government-financing trend	0.252	0.208	-0.097
	[0.284]	[0.245]	[0.287]
Country FE	Yes	Yes	Yes
Date-group FE	Yes	Yes	Yes
Last observed outcome year	2023	2023	2023
Treated jurisdictions	62	62	23
Countries	67	67	30
Observations	324	324	152
R^2	0.310	0.273	0.436

This table shows the primary expanded and secondary national-route financing comparisons. The dependent variable is Δ government financing share, in percentage points, defined as the average of years $g+1$–$g+3$ minus year $g-1$. Panel A begins with 62 treated jurisdictions under the broader definition and then restricts attention to 23 national-route jurisdictions. GDP is measured before the reform; column (2) caps weights at the treated-sample 95th percentile. Coefficients are followed by country-cluster CR2 standard errors in brackets. ***, ** and * denote individual significance at 1%, 5% and 10%, using Satterthwaite tests.

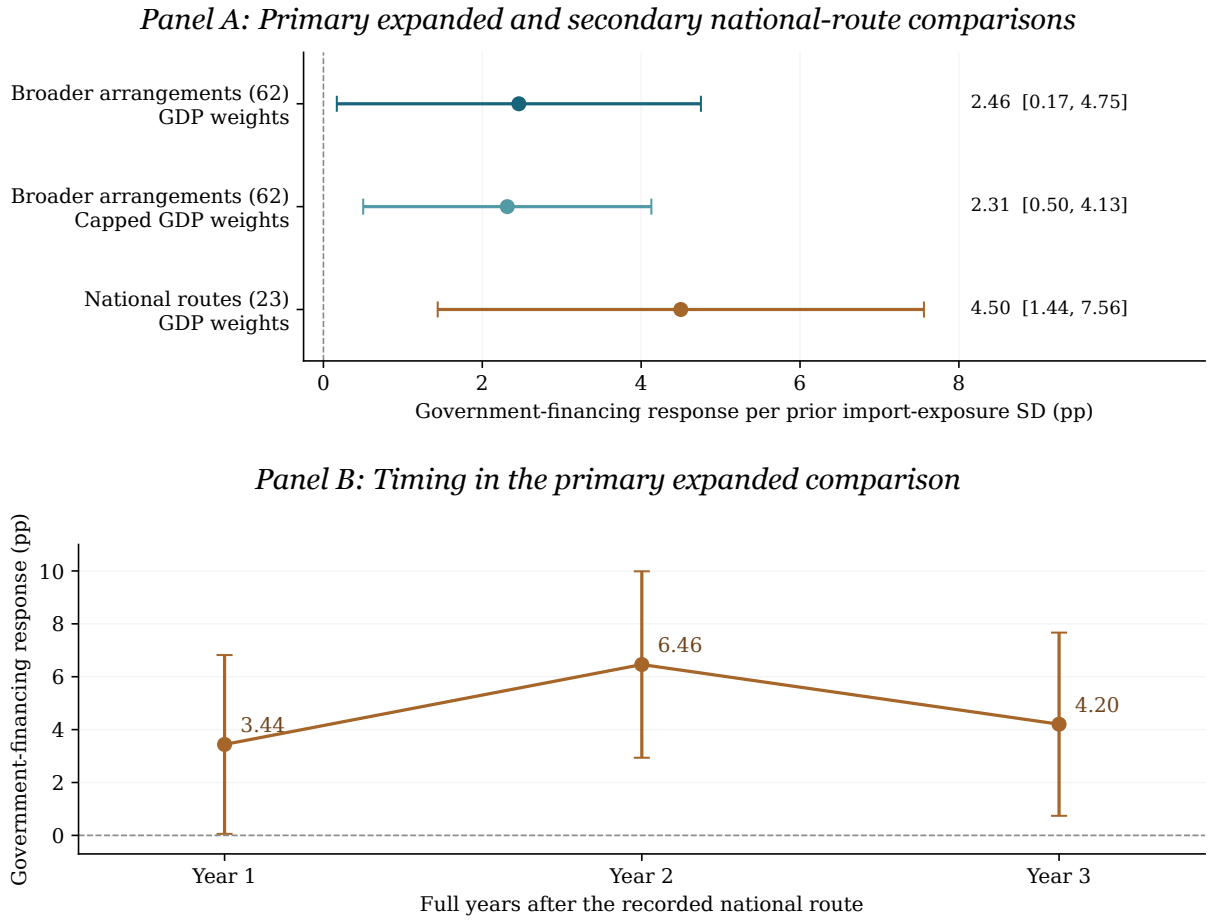


Figure 2: Public-financing responses: primary expanded and secondary national-route samples

This figure shows the public-financing response associated with prior medicine-import dependence. Panel A first reports the primary pooled GDP-weighted estimate for 62 treated jurisdictions, the capped-GDP estimate for the same sample, and the GDP-weighted estimate for 23 national-route jurisdictions, in that order. GDP weights use real GDP per person multiplied by population before the reform; capped weights use the treated-sample 95th percentile. The coefficients are 2.46, 2.31 and 4.50 percentage points. The broader sample contains 67 countries and the national-route sample 30 countries. Panel B uses the same 62-jurisdiction sample and pooled specification as the primary estimates. GDP-weighted annual coefficients are 1.72, 2.71 and 2.95 points, and capped-GDP coefficients are 1.58, 2.68 and 2.69 points. Each line averages to its corresponding three-year coefficient in Panel A. All estimates use the same fixed exposure scale: one standard deviation represents approximately a 2.25-fold difference in prior medicine imports relative to GDP. Bars show individual 95% country-cluster CR2/Satterthwaite intervals. The latest observed outcomes are for 2023.

TABLE 3
Public-financing responses in expanded reliance samples (continued)

Panel B: Secondary equal-country-weighted comparisons

	National routes		Broader arrangements	
Variables	(1)	(2)	(3)	(4)
Specification	Pooled	Date-group	Pooled	Date-group
Reliance × prior import exposure	3.210***	4.702***	-0.021	-0.000
	[0.742]	[1.156]	[0.971]	[1.178]
Documented reliance arrangement	1.542		1.545	
	[1.061]		[0.968]	
Prior import exposure	-1.928**		-0.071	
	[0.560]		[0.461]	
Pre-reform log real GDP per person	0.306	-0.411	1.607**	1.938***
	[0.616]	[0.739]	[0.579]	[0.631]
Pre-reform government-financing share	-0.013	0.027	-0.123**	-0.123**
	[0.056]	[0.069]	[0.042]	[0.044]
Earlier government-financing trend	-0.238	-0.522	-0.034	-0.046
	[0.264]	[0.277]	[0.258]	[0.262]
Country FE	Yes	Yes	Yes	Yes
Date-group FE	Yes	Yes	Yes	Yes
Date-group treatment/exposure terms	No	Yes	No	Yes
Last observed outcome year	2023	2023	2020	2020
Treated jurisdictions	23	23	48	48
Countries	30	30	67	67
Observations	152	152	300	300
R^2	0.316	0.533	0.140	0.239

This table shows the relationship between prior medicine-import exposure and changes in the government share of healthcare expenditure. The dependent variable is Δ government financing share, in percentage points, defined as the average of years $g+1$–$g+3$ minus year $g-1$. Panel A reports pooled comparisons using the extended broader sample (62 treated jurisdictions) and national routes (23 treated jurisdictions). GDP weights use real GDP per person multiplied by population in year $g-1$; comparison weight mass is normalized to treated weight mass within each date group. Column (2) caps these GDP weights at the treated-sample 95th percentile. Panel B retains equal-country-weighted national-route and original broader comparisons; treatment and exposure main effects vary by date group in columns (2) and (4). The broader definition combines national routes, WHO participation and shared European authorization using the earliest documented qualifying event. The outcome is the average over three full post-event years minus the last full pre-event year, in percentage points. One exposure standard deviation represents approximately a 2.25-fold difference in prior medicine imports relative to GDP. Comparisons use later-dated countries. Panel A uses observed outcomes through 2023; the original broader comparison in Panel B uses outcomes through 2020. Coefficients are followed by country-cluster CR2 standard errors in brackets. ***, ** and * denote individual significance at 1%, 5% and 10%, using Satterthwaite tests.

4.2 The same medicine under different national rules

The financing comparison combines arrangements with different conditions for using foreign regulatory work. We next identify what those differences mean for the same applicant. The legal corpus records when documented arrangements appear and which approval procedures they support (Figure 3). Applying these rules to an identical medicine connects the country comparison to the supplier's feasible procedure set in equation (2.1).

Textual analysis first identifies the provisions that recur across countries. Latent Dirichlet allocation groups 65 texts into three dominant wording themes: assessment reports and review, 52.3%; authorization and recognition, 38.5%; and foreign information and submission, 9.2%. Coding 89 national-pathway texts identifies 52 discussing reports or sharing permission and 40 discussing product or dossier matching (Figure 4). The recurring provisions show that reliance combines scientific information with distinct eligibility and documentary requirements.

Following the standardized-applicant approach of Djankov et al. (2002, 2008), we hold the medicine, manufacturer and dossier constant in 94 country cases, then vary foreign approvals, complete reports and sharing permissions. Complete reports and permissions meet an applicable complete-report condition in nine cases; two expressly restrict public-source material. Ten cases require multiple approvals or approval in multiple countries for a selected procedure, while six also offer a one-approval alternative (Figure 4, Panel C). The same applicant therefore faces different documentary conditions and available procedures across national systems.

4.3 The financing environment and household payments

The common-medicine comparison shows how eligibility and documentary conditions change the procedures available to a supplier. We use supplementary national-route regressions, covering 17 treated jurisdictions and 33 countries, to ask how the public response varies with the initial role of households and collective payers. Following the pre-Medicare insurance comparisons of Finkelstein (2007), we include prior import dependence, the household-financed share and income jointly. The import-exposure interaction is 3.00 percentage points and the prior-household-financing interaction is -2.47 points (Table 4). The response is larger where imports are more important and households initially finance a smaller share of care. The initial payer mix thus helps explain where the public-financing association is larger.

A changing payer mix can accompany either different total spending or a redistribution of its financing. To distinguish these accounting margins, we estimate household

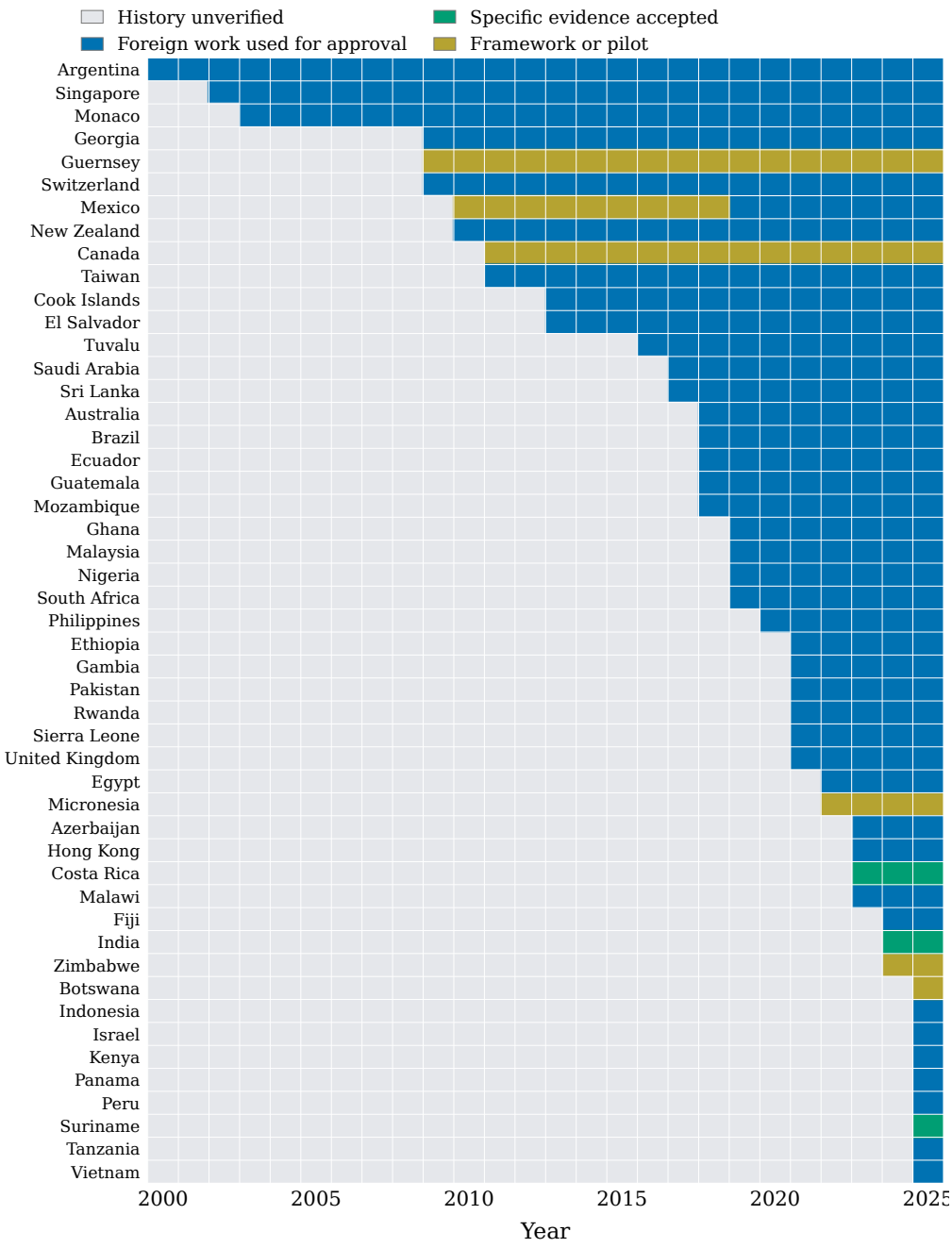


Figure 3: When documented reliance arrangements appear across jurisdictions

This figure shows the country–year distribution of documented reliance arrangements. The 49 displayed jurisdictions have at least one dated arrangement in the legal inventory; the remaining 201 inventory jurisdictions have no resolved dated arrangement in this reconstruction and are omitted for readability. Grey denotes unverified history. Blue groups recognition, abridged assessment, verification, combined routes and WHO collaboration supporting a domestic approval decision. Green denotes acceptance of a specific input; gold denotes an enabling framework or limited pilot. Dates and continuation conventions are described in the Online Appendix. The expanded financing sample additionally uses programme-participation and shared-authorization histories. Colored cells identify documented arrangements

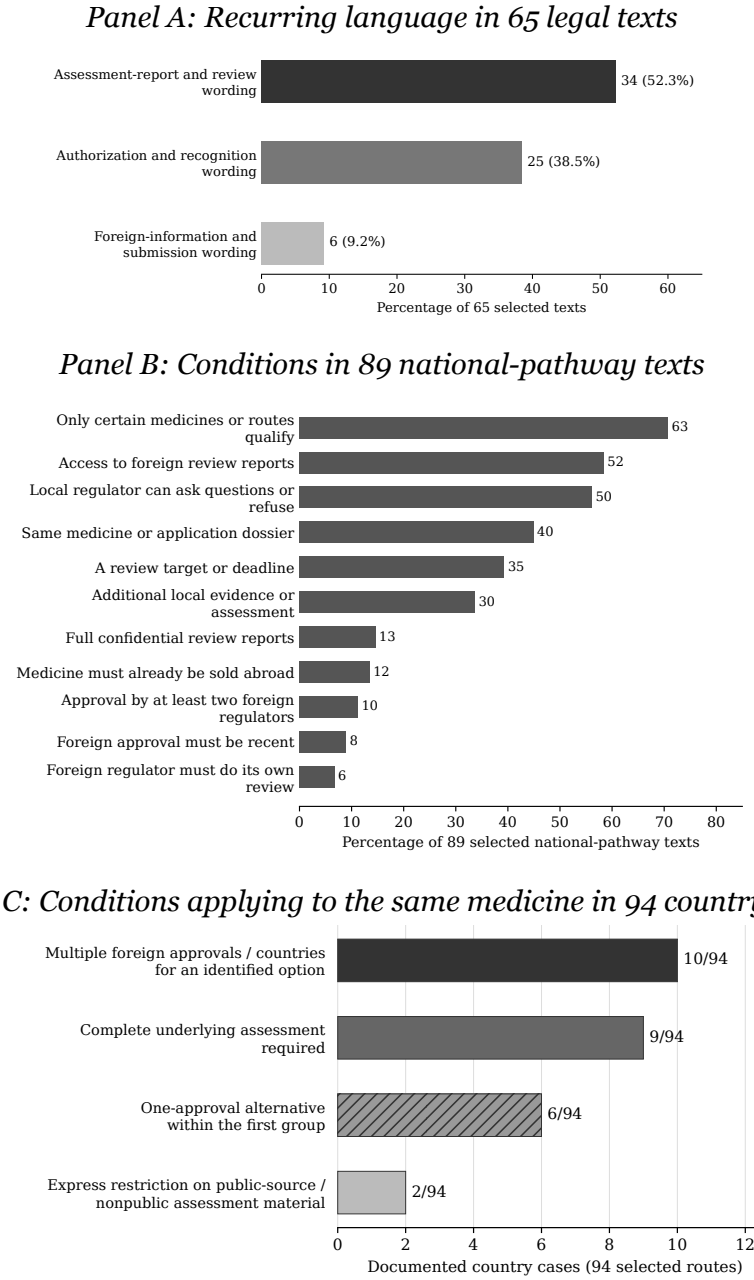


Figure 4: Cross-country legal requirements for foreign regulatory reliance

This figure shows how legal wording translates into conditions for using foreign regulatory work. Panel A groups 65 texts, including 52 English sources and 13 checked translations, by their dominant wording theme. Panel B reports nonexclusive condition counts in 89 national-pathway texts. Panel C applies documentary and approval-count conditions to the identical medicine and dossier in 94 selected country cases; its hatched bar identifies six one-approval alternatives within the ten multiple-approval cases. The Online Appendix identifies those country cases.

TABLE 4
Joint comparisons of import exposure and the financing environment

Variables	(1)	(2)	(3)	(4)
Reliance × prior import exposure	3.574***	2.999***	3.738***	3.004***
	[0.691]	[0.558]	[0.775]	[0.682]
Reliance × prior household share		-2.353***		-2.466***
		[0.767]		[0.758]
Reliance × prior income			-0.815	-1.281
			[0.858]	[0.900]
Documented reliance arrangement	1.458*	1.426*	1.032	0.977
	[0.800]	[0.703]	[0.746]	[0.645]
Prior import exposure	-2.335***	-2.059***	-2.290***	-2.024***
	[0.310]	[0.351]	[0.316]	[0.402]
Prior household share		1.181		1.067
		[0.734]		[0.669]
Prior real income			18.451	10.937
			[11.566]	[11.798]
Pre-reform log real GDP per person	0.745	0.604	-13.860	-7.684
	[0.599]	[0.551]	[9.368]	[9.833]
Pre-reform dependent variable	-0.047	-0.051	-0.042	-0.058
	[0.049]	[0.046]	[0.047]	[0.046]
Earlier dependent-variable trend	-0.514**	-0.428**	-0.446**	-0.375**
	[0.196]	[0.181]	[0.197]	[0.171]
Country FE	Yes	Yes	Yes	Yes
Region FE	No	No	No	No
Date-group FE	Yes	Yes	Yes	Yes
Observations	146	146	146	146
Treated jurisdictions	17	17	17	17
Countries	33	33	33	33
R^2	0.342	0.394	0.364	0.417

This table shows joint comparisons of prior import exposure, household financing and income. The dependent variable is Δ government share of healthcare spending, in percentage points. Each interaction includes its characteristic main effect, with characteristics measured before the documented date. Standard errors are clustered by country. Coefficients are followed by standard errors in brackets. ***, ** and * denote significance at the 1%, 5% and 10% levels, respectively.

payments, total expenditure and financing fractions on identical observations and weights. The 10.3% decline in household spending corresponds to a 1.9% change in total expenditure and an 11.9% decline in the household-financed fraction (Table 5, Panels A–B). Adding prior income and growth gives corresponding changes of -11.1%, 3.2% and -13.9%. The estimates locate the household-payment difference mainly in the allocation of healthcare expenditure across payers.

The national-account decomposition and the household surveys cover different country-periods. Before comparing their outcomes, we ask whether the financing pattern also appears where borrowing is observed. We therefore link financing observations to Findex survey dates and hold country observations, controls and weights constant

across outcomes. On this common support, the exposure coefficient is 5.27 percentage points for the public-financing share; the corresponding point estimates are -2.25 points for the household share and -1.90 points for medical borrowing (Table 5, Panel C). The public-financing gradient also appears in the countries and periods covered by the borrowing surveys.

4.4 Medical borrowing and household financial hardship

The common-support comparison connects financing and borrowing, but covers only part of the available Findex sample. We next ask whether exposure-related borrowing changes also appear across the larger supported national-route sample and after accounting for uneven pandemic financing pressures. The baseline import-exposure interaction is -3.21 percentage points. Allowing pandemic responses to vary with the pre-reform public-financing share gives -5.23 points across ten treated jurisdictions and sixteen countries (Table 6, Panel A). In that adjusted regression, greater prior import dependence is associated with a larger relative decline in medical borrowing. This shows a larger reduction in medical borrowing among more import-dependent countries in the pandemic-adjusted comparison.

Medical borrowing need not capture all financial pressure from paying for care. To examine a broader set of household outcomes, we use WHO financial-protection surveys in a separate policy setting: participation in collaborative registration for prequalified medicines. Controlling for prior income, the baseline outcome and pre-participation external health financing gives import-exposure coefficients of -5.61 percentage points for financial hardship and -5.69 points for its impoverishing-spending component across twelve treated jurisdictions and twenty-two countries (Table 6, Panel B). The WHO programme comparison likewise associates greater import dependence with larger reductions in household financial hardship.

The financing and survey comparisons address complementary parts of the household-payment question. The national-route regressions describe a larger public-financing response with prior import dependence, while the specified borrowing and WHO hardship regressions produce negative exposure gradients in financial strain. The financing and survey patterns are consistent with the model's financing hypothesis, linking the allocation of healthcare payments with household financial protection.

TABLE 5
Household payments, total spending and financing composition

Panel A: Baseline

Variables	(1)	(2)	(3)	(4)	(5)	(6)
Specification	HH spending	Total	HH fraction	Public	Govt. fraction	Govt. share
Documented reliance arrangement	-0.109**	0.018	-0.127**	0.057	0.038	1.799
	[0.042]	[0.042]	[0.058]	[0.058]	[0.031]	[1.083]
Country FE	Yes	Yes	Yes	Yes	Yes	Yes
Region FE	No	No	No	No	No	No
Date-group FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	247	247	247	247	247	247
Countries	37	37	37	37	37	37
R^2	0.460	0.249	0.447	0.191	0.060	0.084

Panel B: Prior income and growth

Variables	(1)	(2)	(3)	(4)	(5)	(6)
Specification	HH spending	Total	HH fraction	Public	Govt. fraction	Govt. share
Documented reliance arrangement	-0.118**	0.032	-0.150**	0.060	0.028	1.339
	[0.049]	[0.046]	[0.066]	[0.061]	[0.030]	[1.101]
Pre-reform log real GDP per person	0.002	0.016	-0.014	0.022	0.006	0.343
	[0.013]	[0.012]	[0.014]	[0.018]	[0.014]	[0.423]
Pre-reform real GDP growth	-0.008	0.029***	-0.037**	0.023**	-0.006	-0.170
	[0.011]	[0.008]	[0.016]	[0.010]	[0.006]	[0.170]
Country FE	Yes	Yes	Yes	Yes	Yes	Yes
Region FE	No	No	No	No	No	No
Date-group FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	247	247	247	247	247	247
Countries	37	37	37	37	37	37
R^2	0.466	0.349	0.516	0.244	0.077	0.108

Panel C: Survey-linked financing and medical borrowing

Outcome	Public share	Household share	Medical borrowing	Log household spending	Log total spending
Arrangement × prior import exposure	5.271**	-2.253	-1.901	-0.033	0.057
	[1.125]	[0.790]	[1.022]	[0.070]	[0.044]
Prior income and baseline borrowing	Yes	Yes	Yes	Yes	Yes
Survey-pair FE	Yes	Yes	Yes	Yes	Yes
Observations	24	24	24	24	24
Countries	12	12	12	12	12
Treated jurisdictions	6	6	6	6	6
R^2	0.822	0.752	0.571	0.646	0.876

This table shows household payments and financing composition. The dependent variables in Panels A–B are Δ log expenditure per person, Δ log financing fractions and Δ government financing share; Panel C uses changes in financing shares and medical borrowing in percentage points and changes in log purchasing-power-adjusted expenditure. Panels A–B report household expenditure, total expenditure, the household-financed fraction, government expenditure, the government-financed fraction and the government share. Panel C links observed Findex country-survey dates to annual financing observations on identical observations, controls and weights. Its first three outcomes are percentage points; the last two are logs of purchasing-power-adjusted expenditure per person. Panel C reports the arrangement–prior-import-exposure interaction and uses country-cluster CR2/Satterthwaite inference. In Panels A–B, the first five outcomes are in logs and the last is in percentage points. All columns within each panel use identical observations and weights. Standard errors are clustered by country. Coefficients are followed by standard errors in brackets. ***, ** and * denote significance at the 1%, 5% and 10% levels, respectively.

TABLE 6
Regulatory reliance and household financial strain

Panel A: Medical borrowing, national arrangements

Variables	Baseline	Pandemic adjustment
Arrangement × prior import exposure	-3.207	-5.227***
	[2.022]	[1.055]
Documented arrangement	1.387	-0.600
	[1.945]	[1.482]
Prior import exposure	-1.486	-1.391
	[0.986]	[1.017]
Pre-reform log real GDP per person	-0.226	-2.488**
	[0.865]	[0.814]
Pre-reform outcome	-0.102	-0.100
	[0.243]	[0.230]
Prior public financing × pandemic overlap		0.227***
		[0.047]
Observations	38	38
Countries	16	16
Treated jurisdictions	10	10
Survey-pair FE	Yes	Yes
R^2	0.726	0.799

Panel B: Financial protection, WHO collaborative registration

Variables	Financial hardship	Impoverishing spending
Arrangement × prior import exposure	-5.608**	-5.695***
	[1.066]	[0.766]
Documented arrangement	5.538**	5.532**
	[2.295]	[2.053]
Prior import exposure	-0.137	-0.923
	[1.056]	[1.065]
Pre-reform log real GDP per person	-5.319**	-5.267**
	[1.869]	[1.681]
Pre-reform outcome	-0.213	-0.278*
	[0.131]	[0.118]
Pre-reform external health financing (%)	-0.275**	-0.231*
	[0.097]	[0.098]
Observations	40	40
Countries	22	22
Treated jurisdictions	12	12
Survey-pair FE	Yes	Yes
R^2	0.762	0.812

This table shows exposure-related changes in household financial strain. The dependent variable is Δ medical borrowing in Panel A and Δ financial hardship or impoverishing spending in Panel B, all in percentage points between the indicated survey waves. Panel A uses Global Findex medical borrowing; Panel B uses observed WHO financial-protection survey estimates and participation in the WHO collaborative registration programme for prequalified medicines. Outcomes are percentage points. Prior exposure is the mean log medicine-import-to-GDP ratio over $g-4$–$g-2$, expressed on the original fixed standard-deviation scale. The pandemic adjustment interacts prior public financing with the change in the fraction of survey-recall days falling in 2020–2021. Panel B additionally controls for external health financing averaged before participation. Country changes remove time-invariant country differences; reform-year/survey-pair fixed effects compare the same survey waves. Brackets contain country-cluster CR2 standard errors; ***, ** and * refer to individual Satterthwaite tests at 1%, 5% and 10%.

4.5 Alternative explanations and regulatory scope

The preceding results show financing and household-outcome gradients by prior import dependence. The remaining question is how these associations change when observed economic differences and common shocks are taken into account. We first use the supplementary 17-jurisdiction national-route comparison to examine prior income, outcome paths, demographic composition, debt and macroeconomic conditions. The financing-exposure coefficient is 3.57 points in the baseline and 3.64 points when income, prices and exchange rates are included (Table 7). The association remains positive after accounting for these economic conditions.

Medicine-import dependence may covary with broader trade integration or with countries' exposure to pandemic shocks. We address these parallel explanations with targeted controls. The financing-exposure coefficient is 3.51 points with reported mortality controls, 2.97 points with containment stringency and 2.95 points with both (Table 8). Adding machinery-import or total-import exposure gives coefficients of 3.30 and 2.99 points (Online Appendix). The financing gradient also remains positive conditional on pandemic burden and broader trade integration.

Regulatory coverage and comparison weights.

The control comparisons leave the definition of reliance unchanged. We now ask how the reported financing gradient varies when participation histories, country weights and outcome horizons differ. Extending WHO records increases the broader sample to 62 treated jurisdictions and gives coefficients of 0.52 points in the pooled model and 0.70 points with date-group-specific responses (Table 9). Population weighting gives 1.83 and 1.46 points, while extending the original 48-jurisdiction comparison to six post-event years gives 0.79 and 1.61 points. Across the reported broader-sample comparisons, the GDP-weighted specification gives the largest three-year financing-exposure estimate.

Participation dates describe programme availability, leaving a separate question about observed regulatory activity. To document that margin, we examine WHO registration records, which identify 964 national registrations across 34 countries, covering 274 product identifiers and 941 distinct product–country pairs.[1] The register links medicines and authorization holders to destinations and reported registration dates. These records document use of a named assessment-sharing pathway across multiple products and destinations.

[1]Source: WHO, *Products Registration Update*, March 2024, available at https://extranet.who.int/prequal/sites/default/files/document_files/Products%20Registration%20Update%20-%20March%202024%20-%20sk.xlsx. National totals exclude CARICOM as a separate country and retain one undated national record.

TABLE 7
Public-financing responses with economic controls

Variables	Baseline	Demography	Public debt	Macro controls
Reliance × prior import exposure	3.574***	3.675***	3.573***	3.637***
	[0.691]	[0.687]	[0.669]	[0.890]
Documented reliance arrangement	1.458*	1.148	1.168	1.321*
	[0.800]	[0.855]	[0.777]	[0.764]
Prior import exposure	-2.335***	-2.167***	-2.339***	-2.282***
	[0.310]	[0.466]	[0.299]	[0.304]
Pre-reform log real GDP per person	0.745	0.462	0.629	0.662
	[0.599]	[0.717]	[0.610]	[0.722]
Pre-reform dependent variable	-0.047	-0.028	-0.040	-0.035
	[0.049]	[0.050]	[0.047]	[0.038]
Earlier dependent-variable trend	-0.514**	-0.494**	-0.468**	-0.521**
	[0.196]	[0.207]	[0.197]	[0.225]
Pre-reform real GDP growth		-0.247	-0.233	-0.342
		[0.186]	[0.169]	[0.207]
Pre-reform population aged 65+ (%)		0.052		
		[0.102]		
Pre-reform log population		0.309		
		[0.520]		
Pre-reform public debt/GDP			0.010	
			[0.013]	
Δ log real GDP per person				12.920*
				[6.451]
Δ log consumer prices				-3.662
				[7.425]
Δ log exchange rate				3.664
				[3.212]
Country FE	Yes	Yes	Yes	Yes
Region FE	No	No	No	No
Date-group FE	Yes	Yes	Yes	Yes
Observations	146	146	146	146
Treated jurisdictions	17	17	17	17
Countries	33	33	33	33
R^2	0.342	0.358	0.354	0.382

This table shows supplementary national-route financing-exposure responses with successively different economic controls. The dependent variable is Δ government share of healthcare spending, in percentage points. The exposure interaction uses the fixed pre-reform medicine-import scale. Baseline income, outcome level and trend enter every column. Demography adds age composition and population; the debt column adds pre-reform public debt; the final column conditions on changes in real income, prices and exchange rates. Country-cluster standard errors appear in brackets. ***, ** and * denote individual significance at 1%, 5% and 10%. Online Appendix reports the full control comparisons.

TABLE 8
Import exposure and public financing conditional on common shocks

Variables Specification	(1) Baseline	(2) Mortality	(3) Stringency	(4) Both	(5) Macro
Reliance × prior import exposure	3.574***	3.510***	2.965***	2.948***	3.751***
	[0.691]	[0.700]	[0.700]	[0.706]	[0.915]
Documented reliance arrangement	1.458*	1.512*	1.697**	1.711**	1.569*
	[0.800]	[0.828]	[0.783]	[0.797]	[0.774]
Prior characteristic	-2.335***	-2.269***	-1.935***	-1.909***	-2.319***
	[0.310]	[0.325]	[0.438]	[0.456]	[0.324]
Pre-reform log real GDP per person	0.745	0.749	0.381	0.392	0.900
	[0.599]	[0.602]	[0.495]	[0.504]	[0.667]
Pre-reform dependent variable	-0.047	-0.056	-0.052	-0.056	-0.044
	[0.049]	[0.051]	[0.047]	[0.049]	[0.043]
Earlier dependent-variable trend	-0.514**	-0.461**	-0.322*	-0.298*	-0.581**
	[0.196]	[0.194]	[0.159]	[0.169]	[0.222]
Δ reported COVID mortality		0.000		0.000	
		[0.000]		[0.000]	
Δ containment stringency			0.239***	0.233***	
			[0.046]	[0.050]	
Δ log real GDP per person					9.693
					[6.779]
Δ log consumer prices					-1.149
					[6.388]
Δ log exchange rate					2.934
					[3.056]
Country FE	Yes	Yes	Yes	Yes	Yes
Region FE	No	No	No	No	No
Date-group FE	Yes	Yes	Yes	Yes	Yes
Observations	146	146	137	137	146
Treated jurisdictions	17	17	16	16	17
Countries	33	33	33	33	33
R^2	0.342	0.349	0.452	0.454	0.361

This table shows supplementary national-route the import-exposure financing comparison with mortality, containment stringency, and macroeconomic changes. The dependent variable is Δ government share of healthcare spending, in percentage points. Prior exposure is measured before the documented date. Standard errors are clustered by country. Coefficients are followed by standard errors in brackets. ***, ** and * denote significance at the 1%, 5% and 10% levels, respectively.

National legal profiles and initial resources.

The timing and coverage comparisons concern changes around documented arrangements. A parallel question is how financing levels differ across countries with different resources and legal profiles. Following Djankov et al. (2002), we use a cross-sectional regression including national legal indicators, income, population, age composition and region effects. Across 84 jurisdictions, the log-income coefficient is 9.04 percentage points and the assessment-report clause coefficient is 3.11 points in the joint specification (Table 10). The income association places economic resources alongside legal profiles when interpret-

TABLE 9

Later participation histories, alternative weights and joint financing estimates

	Pooled	Date-group-specific
Panel A: Extended history, 62 treated jurisdictions		
Country weights	0.521	0.700
	[0.933]	[1.025]
Equal weight per date group	0.360	0.883
	[0.905]	[1.044]
Balanced repeated country roles	0.457	0.620
	[0.947]	[1.048]
Population weights	1.826	1.461
	[1.284]	[1.194]
Square-root population weights	1.130	1.185
	[0.929]	[0.873]
Countries	67	67
Country–date-group observations	324	324
Last observed outcome year	2023	2023
Panel B: Original 48 treated jurisdictions, longer windows		
First 3 full post-event years	-0.021	-0.000
	[0.971]	[1.178]
First 4 full post-event years	0.333	0.455
	[1.040]	[1.227]
First 5 full post-event years	0.586	1.206
	[1.090]	[1.279]
First 6 full post-event years	0.787	1.611
	[1.147]	[1.230]
Observations: three-/four-/five-/six-year windows	300 / 268 / 232 / 203	
Panel C: Joint estimation, 62 treated jurisdictions		
Seemingly unrelated regressions: government share	0.498	0.679
	[0.938]	[1.035]
Observations per equation	324	324
Countries	67	67
Prior income, outcome level and trend	Yes	Yes
Date-group FE	Yes	Yes
Date-group treatment/exposure terms	No	Yes

This table shows financing-exposure coefficients using later participation histories, alternative weighting schemes and joint financing equations. The reported dependent variable is Δ government share of healthcare spending, in percentage points. All coefficients are percentage points in the government share per fixed pre-event import-exposure standard deviation. Panel A retains three complete post-event years and varies the weights on unchanged observations. Panel B retains all 48 original treated jurisdictions; comparison support changes with the window. Panel C jointly estimates government and household financing shares and log total spending, with equation-specific prior outcome controls. Brackets contain country-cluster CR2 standard errors. Stars denote coefficient-specific Satterthwaite significance at 1%, 5% and 10%.

ing country differences. Economic resources and documentary requirements jointly characterize these cross-country financing differences.

TABLE 10
Legal requirements and the public-financing share

Variables	(1)	(2)	(3)	(4)
Assessment-report clauses	2.544	2.481	3.861	3.114
	[3.086]	[3.085]	[3.347]	[3.830]
Multiple-approval clauses				-3.835
				[8.710]
Product-sameness clauses				-1.351
				[4.452]
Local-evidence clauses				5.675
				[4.187]
Domestic-discretion clauses				-1.557
				[4.194]
Log real GDP per person	10.505***	9.139***	9.057***	9.038***
	[1.332]	[1.789]	[2.338]	[2.435]
Log population	-1.198	-1.132	-1.387	-1.215
	[0.989]	[1.027]	[1.127]	[1.287]
Population aged 65+ (%)		0.333	0.336	0.379
		[0.286]	[0.463]	[0.481]
Country FE	No	No	No	No
Region FE	No	No	Yes	Yes
Date-group FE	No	No	No	No
Observations	84	84	84	84
Countries	84	84	84	84
R^2	0.556	0.562	0.570	0.581

This table shows the relationship between national legal requirements and the government financing share in 2023, in percentage points. The dependent variable is the government share of healthcare spending in 2023, in percentage points. Columns add age composition, region effects, and the five legal indicators jointly. The sample contains 84 national-rule jurisdictions. Standard errors use HC3. Coefficients are followed by standard errors in brackets. ***, ** and * denote significance at the 1%, 5% and 10% levels, respectively.

4.6 A proposed mechanism: imported treatments and public financing

The preceding comparisons establish a larger public-financing response in more import-dependent countries and connect the payer mix to household financial strain. We posit an access-and-public-financing mechanism: usable reliance procedures improve manufacturers' opportunities to seek domestic authorization, while public coverage creates demand for the resulting treatment options. Following the profit-incentive logic of Acemoglu and Linn (2004), the commercial opportunity depends on the purchasers willing to fi-

nance treatment. The model therefore motivates examining expenditure levels alongside financing shares.

In the GDP-weighted 62-jurisdiction comparison, an approximately 2.25-fold difference in prior medicine imports relative to GDP is associated with 8.1% higher government healthcare expenditure per person, 2.7% higher total expenditure and 2.5% lower household expenditure following documented reliance arrangements, relative to comparison countries (Table 11, Panel A). Government expenditure grows faster than overall healthcare spending, giving public payers a larger role in financing care. This pattern is consistent with the model's prediction that reliance can make imported treatments easier to finance publicly.

The financing-share equations locate the corresponding reallocation across payers. On the same observations and weights, the government share rises by 2.46 percentage points, while the household share falls by 0.96 points and other financing sources by 1.50 points (Table 11, Panel B). The model allows public coverage to expand both through additional treatment and through a transfer of an existing treatment bill. The headline financing response is therefore accompanied by a larger public contribution to healthcare expenditure.

TABLE 11
Domestic public financing and expenditure composition

Panel A: Healthcare expenditure per person (logs)

Variables	Government	Total	Households
Reliance × prior import exposure	0.078	0.027	-0.025
	[0.067]	[0.069]	[0.065]
Documented reliance arrangement	-0.032	-0.076	-0.071
	[0.050]	[0.041]	[0.038]
Prior import exposure	0.014	0.043	0.112**
	[0.058]	[0.043]	[0.035]
Pre-reform log real GDP per person	0.010	-0.013	-0.006
	[0.037]	[0.034]	[0.032]
Pre-reform government-financing share	-0.002	0.001	-0.002
	[0.003]	[0.003]	[0.002]
Earlier government-financing trend	0.037	0.034	0.032
	[0.030]	[0.028]	[0.022]
Implied percentage change	8.1%	2.7%	-2.5%
Country FE	Yes	Yes	Yes
Date-group FE	Yes	Yes	Yes
Treated jurisdictions	62	62	62
Countries	67	67	67
Observations	324	324	324
R^2	0.351	0.427	0.451

Panel B: Sources of healthcare financing (percentage points)

Variables	Government	Households	Other sources
Reliance × prior import exposure	2.460**	-0.963	-1.497
	[0.774]	[1.018]	[1.245]
Country FE	Yes	Yes	Yes
Date-group FE	Yes	Yes	Yes
Treated jurisdictions	62	62	62
Countries	67	67	67
Observations	324	324	324
R^2	0.310	0.205	0.337

This table shows the expenditure and financing components of the GDP-weighted 62-jurisdiction comparison. The dependent variables are Δ log government, total and household expenditure per person in Panel A and Δ government, household and other financing shares in Panel B, in percentage points. Panel A reports log government, total and household healthcare expenditure per person, measured in current US dollars; implied percentage changes equal $100[\exp(\widehat{\beta}) - 1]$ for the reliance–import-exposure interaction. Panel B reports financing-share changes in percentage points. Other sources combine external financing and remaining private sources. All equations retain the same 324 observations, pre-reform GDP weights, date groups and regressors as the headline public-share estimate. Baseline income, the government-financing level and its earlier trend enter every equation. One exposure standard deviation corresponds to approximately a 2.25-fold difference in prior medicine imports relative to GDP. The outcome change compares the first three full post-event years with the preceding year. Brackets contain country-cluster CR2 standard errors; ***, ** and * denote individual significance at 1%, 5% and 10% using Satterthwaite tests.

5 Conclusion

We link a legal corpus covering 250 countries and areas to pharmaceutical imports and healthcare financing. Applying the rules to the same medicine in 94 country cases separates foreign approval credentials, access to scientific reports and permission to share them. These are distinct policy choices governing the procedures available to an otherwise identical applicant.

In the GDP-weighted comparison of 62 treated jurisdictions, a one-standard-deviation increase in prior medicine-import dependence is associated with a 2.46-percentage-point larger increase in the government financing share. The coefficient rises to 4.50 points in the secondary 23-jurisdiction national-route sample. Household surveys associate greater import dependence with a 5.23-point larger decline in medical borrowing; the separate WHO comparison gives declines of 5.61 points in financial hardship and 5.69 points in impoverishing spending. Together, these findings connect regulatory cooperation to a larger public-financing role and reduced household financial strain.

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A Formal model and proofs

This appendix proves the three propositions in Section 2.4. The internationally available stock of medicines is fixed, procedure menus are finite, and the comparisons hold the remaining market primitives constant. The Online Appendix gives the report-value calculations, detailed eligibility conditions, payer solution and additional comparative statics.

A.1 Usable information and application value

Assessment assumptions. Let $h > 0$ denote domestic expertise, $R \geq 0$ accessible foreign precision and $\phi(h) = h/(h+\kappa)$, with $\kappa > 0$. The common-component assessment objective is

$$\min_{e \geq 0} \left\{ \frac{w}{T_0 + \phi(h)R + e} + \frac{c}{h}e \right\}, \qquad w, c, T_0 > 0. \tag{A.1}$$

The local scientific component is separable and unaffected by R. Foreign information must be lawfully available; an approval credential by itself need not supply that information.

Proof of Proposition 2.1. The first derivative is $-w/(T_0 + \phi R + e)^2 + c/h$, and the second is positive. Thus the unique optimum is

$$e^* = \left[\sqrt{wh/c} - T_0 - \phi(h)R \right]_+ . \tag{A.2}$$

While effort is positive, $\partial e^*/\partial R = -\phi(h)$: accessible reports replace repeated scientific work. Total precision remains $\sqrt{wh/c}$ in that region. After effort reaches zero, additional reports increase precision instead. The separable local assessment is unchanged.

For application value, let $\mathcal{P} \subseteq \mathcal{P}'$ denote the old and expanded menus. On every old procedure hold authorization probability a_p fixed, and suppose delay and total private cost satisfy $d'_p \leq d_p$ and $F'_p \leq F_p$. Holding operating value $\Pi \geq 0$ fixed gives

$$a_p e^{-\rho d'_p}\Pi - F'_p \geq a_p e^{-\rho d_p}\Pi - F_p.$$

Taking the maximum over the enlarged menu and the zero outside option preserves this inequality. Value rises strictly if a new or improved procedure exceeds the old best value. An additional credential can therefore have procedural value even when its scientific information overlaps an existing report. The private-cost comparison includes documentary procurement costs; lower regulator effort affects entry only through the private requirements or delays that the firm faces. □

A.2 Purchasing opportunities and entry composition

For category $k \in \{F, A\}$, let $x_k \geq 0$ be the potential pool of first-family or additional-product opportunities. Applicants draw an additive, route-independent cost c from a continuous cumulative distribution Ψ_k, independently of authorization. Extend the distribution by zero below its support and one above it. For fixed authorization probability a_k, define the best return before this applicant cost as

$$W_k = \max_{p \in \mathcal{P}_k} \{a_k e^{-\rho d_{kp}} \Pi_k - f_{kp}\}.$$

An empty menu gives no applications. Otherwise the firm applies when its applicant cost is below W_k; ties have zero mass.

Proof of Proposition 2.2. Every available procedure's return is weakly increasing in Π_k and weakly decreasing in f_{kp}. A maximum preserves these inequalities. Since Ψ_k is nondecreasing, expected applications $x_k \Psi_k(W_k)$ and expected authorizations $N_k = a_k x_k \Psi_k(W_k)$ weakly increase with profitable purchasing opportunities or a reduction in application costs. Different pools, cost distributions and menus permit different responses across first families and additional options.

If c is uniform on $[0, \bar{c}_k]$, the cutoff is interior, and the active procedure has $W_k = \bar{W}_k + \delta_k r$, then

$$N_k = \frac{a_k x_k}{\bar{c}_k}(\bar{W}_k + \delta_k r), \qquad \frac{\partial N_k}{\partial r} = \frac{a_k x_k \delta_k}{\bar{c}_k}. \tag{A.3}$$

For $\delta_k \geq 0$ this derivative is nonnegative and is larger with a larger eligible foreign-product pool, holding the other primitives fixed. At a support boundary the corresponding one-sided comparison applies. Higher market size raises operating value when net treatment margins are nonnegative; its interaction with reform depends additionally on the cost density and the available pool. The proposition therefore does not impose the same response on first-family and additional-product opportunities. □

A.3 Public coverage and financing incidence

The payer selects an expected transfer τ for existing household bills and additional public purchases y_k. Its objective is

$$Q = \alpha\tau - \tfrac{1}{2}\eta\tau^2 + \sum_k (v_k y_k - \tfrac{1}{2}\xi_k y_k^2) - \lambda Y - \tfrac{1}{2}\chi Y^2, \quad Y = \tau + \sum_k y_k,$$

subject to $0 \le \tau \le \ell L$, $0 \le y_k \le b_k N_k$ and $Y \le K$. Here $\eta, \xi_k > 0$, $\lambda, \chi \ge 0$ and $K \ge 0$. Its Hessian is $-\operatorname{diag}(\eta, \xi_F, \xi_A) - \chi \mathbf{1}\mathbf{1}'$, which is negative definite. The compact convex feasible set therefore gives a unique continuation choice. Treatment value, external support and the budget govern this choice.

Proof of Proposition 2.3. Let initial total expenditure be $T_0 > 0$. Additional treatment expenditure B_k has fixed government and household fractions g_k and h_k; the remaining fractions are external and other financing. A transfer moves an existing bill between payers, so

$$G = G_0 + \sum_k g_k B_k + \tau, \qquad H = H_0 + \sum_k h_k B_k - \tau, \qquad T = T_0 + \sum_k B_k.$$

For any differentiable reliance response, holding initial spending and these fractions fixed, the quotient rule yields

$$S_G' = \frac{G'T - GT'}{T^2} = \frac{\tau' + \sum_k (g_k - S_G) B_k'}{T}, \qquad S_G = G/T. \tag{A.4}$$

Since $T > 0$, public coverage raises the government share through τ'. Additional treatment raises that share when its government-financed fraction exceeds the existing share and lowers it when the fraction is smaller. Meanwhile $H' = \sum_k h_k B_k' - \tau'$, so household payments fall precisely when the transfer exceeds additional household-financed treatment. These statements concern the marginal purchaser and hold along any consistent differentiable response. If financing fractions vary, the government-share numerator also contains $\sum_k B_k g_k'$, as derived in the Online Appendix. □