Reliance on Foreign Drug Assessments and Domestic Healthcare Financing*

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Abstract

We examine whether international cooperation can ease the financial burden of healthcare on households by helping governments finance a larger share of care. Using a GDP-weighted stacked difference-in-differences design comparing 69 adopting jurisdictions with later adopters, we find that higher prior medicine imports relative to GDP are associated with larger increases in the government share of healthcare spending following regulatory reliance. This association is stronger when we restrict treatment to national reliance routes. Expenditure decompositions show that government spending increases faster than total spending in more import-dependent countries. Greater import dependence is associated with larger declines in household medical borrowing and financial hardship following reliance arrangements. These findings are consistent with reliance lowering barriers to medicine entry and expanding treatment options governments can finance through public coverage.

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.

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1 Introduction

An extensive literature documents how regulation shapes pharmaceutical firms' decisions about which countries to supply and when to launch. Price controls can delay launches, while international reference pricing gives manufacturers an incentive to withhold medicines from lower-price markets (Kyle, 2007; Maini and Pammolli, 2023). A separate literature shows that public drug insurance can lower pharmaceutical prices and increase use (Duggan and Scott Morton, 2010). These studies demonstrate that entry rules and payment arrangements influence pharmaceutical markets. An important but understudied form of regulatory cooperation is regulatory reliance. Regulatory reliance allows a domestic authority to use assessments completed by a trusted foreign regulator when making its own authorization decision. WHO recommends this practice to reduce duplicated work and make better use of limited regulatory expertise (World Health Organization, 2021). Whether regulatory reliance changes how healthcare costs are shared between governments and households remains a puzzle.

Who pays for healthcare matters because household payments expose patients to financial strain, while public coverage spreads treatment costs across the population and creates demands on government budgets (Finkelstein and McKnight, 2008; Finkelstein, Hendren, and Luttmer, 2019). Regulatory reliance can influence this allocation by changing the treatment options available for domestic purchase. Reducing repeated assessment can lower manufacturers' application costs and waiting times, making additional markets commercially viable. Public payers may then finance additional treatments or extend coverage to medicines previously purchased by households. Where public expenditure grows faster than total healthcare spending, the government financing share increases. This channel is particularly relevant in countries that depend heavily on imported medicines, where domestic treatment options depend on products assessed abroad. Our research question is whether reliance arrangements are followed by a larger shift toward government financing in countries with greater prior medicine-import dependence.

To answer the question, we first manually build a corpus of regulatory reliance provisions from official sources, using a geographic search frame of 250 countries and areas. We construct a treatment calendar for 2000–2025. The corpus contains 439 national passages from 134 jurisdictions and nine shared-system passages. We link this legal record to international trade and health-expenditure data. Treatment identifies the availability of an institutional arrangement through which domestic authorization can draw on foreign or jointly produced regulatory work. It records institutional access rather than individual applications, approvals or reimbursement decisions. A country becomes treated at its first

documented qualifying event, whether (1) a national reliance route, (2) participation in WHO collaborative registration for prequalified medicines, or (3) entry into the EU/EEA shared authorization system. Our primary stacked DiD comparison includes 69 treated jurisdictions. We use not-yet-treated countries as comparisons (Callaway and Sant'Anna, 2021).

Our outcome variable is the government share of total healthcare expenditure. We measure its percentage-point change from the year before reliance to the average of the first three full years afterward, excluding the event year. Assuming parallel trends in the absence of reliance, we compare this change with the corresponding change in countries that adopt reliance later. Our primary estimand is how this treated–comparison difference varies with prior medicine-import dependence. We next examine the proposed financing channel by decomposing total healthcare spending into government and household components. To supplement these accounts, we use secondary survey data to examine household financial strain following reliance arrangements.

We find that greater prior medicine-import dependence is associated with a larger increase in government financing following reliance arrangements. In our main sample, a roughly 2.25-fold difference in prior medicine imports relative to GDP is associated with a 2.42-percentage-point larger increase in the government share of healthcare spending. When we exclude mass waves of WHO participation and shared European authorization and count only national regulatory reliance programs, we obtain a sample of 30 treated jurisdictions and a GDP-weighted coefficient of 4.28 percentage points. We then complement these estimates with cross-sectional comparisons of national legal requirements and household survey analyses. The survey comparisons show that greater prior import dependence is associated with larger declines in medical borrowing and financial hardship following reliance arrangements. These findings provide new evidence that the public-financing response to regulatory cooperation is larger where imported medicines are more important.

We construct an analytical model to explain how reliance can change who pays for healthcare, adapting the market-size and profit-incentive framework of Acemoglu and Linn (2004) to medicines that already exist internationally. It explains why a reform that reduces regulatory duplication can increase demands on public budgets. Lower application costs and shorter waiting times can make additional medicines commercially viable, creating treatment options that governments may choose to cover. Whether households benefit financially depends on how this coverage expands. Public spending can grow alongside household payments when treatment use increases, while household bills fall only when public coverage replaces more existing household expenditure than the additional

treatment requires households to pay. We therefore posit that reliance can improve household financial protection when easier market entry is accompanied by public coverage that absorbs a greater share of treatment costs.

For robustness, we adjust for economic conditions that may influence both regulatory choices and healthcare spending and continue to find a positive financing association. In supplementary national-route regressions, the financing interaction remains positive after controlling for changes in income, consumer prices and exchange rates. We then examine the model's proposed public-financing mechanism using government, total and household spending on the same sample and weights as the headline comparison. For the same prior-import-dependence contrast, the estimates imply 7.8% higher government healthcare expenditure per person, 2.8% higher total expenditure and 2.7% lower household expenditure. Government spending grows faster than total spending, providing evidence of a larger public contribution to the financing of care, while households spend less.

Our main finding of a larger public-financing response in more import-dependent countries continues to hold in national-route regressions that account for macroeconomic conditions, pandemic pressures and general trade exposure, and when individual countries are omitted. We examine pre-event outcome patterns, alternative event dates and comparison-group construction to assess the credibility of the identifying comparison. Additional analyses vary country weights and the number of years after adoption to establish how the estimates depend on the weighting scheme and response horizon.

Our corpus distinguishes (1) abridged review, which uses foreign findings alongside selected domestic assessment, (2) verification, which checks product matching and route conditions, and (3) recognition, which accepts a foreign authorization without repeating its scientific assessment. DiD treatment begins at the first documented qualifying national route, WHO collaborative-registration participation or EU/EEA shared authorization, rather than a mention of reliance alone. Textual analysis of 439 passages from 134 jurisdictions also identifies themes concerning registration and supporting information, authorization and recognition, and assessment reports and reliance. Among 89 national-rule profiles, 70.8% specify eligible products or procedures and 56.2% retain domestic decision or further-review powers. Reliance commonly involves continuing domestic checks rather than instant approval. The least common coded feature concerns complete or non-public reports, appearing in 14.6% of profiles. This highlights a gap between recognizing foreign decisions and expressly providing access to the detailed scientific information behind them.

To further examine how the financing pattern relates to household financial strain, we use 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 borrowing for medical expenses following national reliance arrangements. In the separate WHO collaborative-registration comparison, controlling for prior external health financing gives declines of 5.61 percentage points in financial hardship and 5.69 points in impoverishing spending for the same standardized import-dependence measure. Matching Findex observations to health accounts also gives a positive public-financing gradient in the same countries and survey periods. These findings provide new evidence of reduced household financial strain in more import-dependent countries in these survey comparisons.

Our contribution is to connect cooperation in pharmaceutical authorization to healthcare financing, with prior medicine-import dependence identifying the central dimension of heterogeneity. We contribute to two strands of literature. First, we extend comparative research on legal institutions and pharmaceutical entry. Following the standardized-case approach of Djankov, La Porta, Lopez-de Silanes, and Shleifer (2002); Djankov, Hart, McLiesh, and Shleifer (2008), we apply documented rules to the same medicine in 94 countries, holding the manufacturer, product and application dossier constant. We separate approval credentials, scientific reports and permission to share them, following comparative institutional research that distinguishes individual legal requirements (Djankov, La Porta, Lopez-de Silanes, and Shleifer, 2003; La Porta, Lopez-de Silanes, and Shleifer, 2006; Bosio, Djankov, Glaeser, and Shleifer, 2020). 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 (Gentzkow, Kelly, and Taddy, 2019). Among the 89 coded national-route jurisdictions, at least 39.3% explicitly name the US FDA or European central authorization bodies as references, and 37.1% name multiple foreign reference authorities including at least one of these systems. These patterns show how US and European regulatory work enters wider international reference networks. Across five matched route menus, an additional qualifying foreign approval is associated with a 46.7% shorter published review target. We quantify the procedural value of foreign approval alongside the pricing and entry incentives studied by Kyle (2007), Maini and Pammolli (2023) and Wang, Li, and Anupindi (2023).

Second, we connect regulatory cooperation to the allocation of healthcare costs and household financial protection. Public insurance can protect households from medical bills (Finkelstein and McKnight, 2008) and affect pharmaceutical prices and use (Duggan and Scott Morton, 2010). Evidence and negotiation influence reimbursement (Yapar, Chick, and Gans, 2025), while pricing policies can benefit manufacturers, patients and payers differently (Adida, 2024; Feng and Maini, 2024). We bring the approval pro-

cess into this financing question by examining government spending, household payments and financial strain together. The expanded 69-jurisdiction comparison shows a larger public-financing response with greater prior medicine-import dependence. The national-route and survey comparisons connect that pattern to domestic approval arrangements and household financial pressure.

2 Institutional details and hypotheses

2.1 How drug approval and market entry work

Developing a new medicine requires years of testing before it can be approved. The FDA estimates that studying and testing a new drug, including laboratory, animal and clinical testing, takes about eight and a half years before approval (U.S. Food and Drug Administration, 2026). Clinical research generally proceeds through three phases. Even Tamiflu's relatively rapid development took about two and a half years from the start of clinical trials to its first approval in 1999 (Gilead Sciences, Inc. and Roche, 2005). Its adult treatment studies included two Phase III trials involving 1,355 participants (U.S. Food and Drug Administration, 2005). Drug approval protects patients by requiring evidence of safety and efficacy. It also imposes costs that manufacturers must incur before earning revenue (Peltzman, 1973). Whether a manufacturer supplies a country therefore depends on both the approval requirements and the expected return from that market. Price regulation can further discourage entry or delay launch (Kyle, 2007).

In the United States, the Food and Drug Administration (FDA) reviews the manufacturer's evidence on quality, safety and effectiveness. A new drug application brings together laboratory and clinical findings, manufacturing information and proposed prescribing instructions. The FDA first checks whether the submission is complete enough for substantive review. For new molecular entities and original biologics applications, its PDUFA VII performance goals are to review and act on 90% of standard applications within ten months after the 60-day filing date, or six months for priority applications. The initial filing period therefore brings these first-cycle targets to roughly twelve and eight months from submission. Review can involve further questions, manufacturing inspections and changes to the proposed label. The target concerns a regulatory action, which can request further work rather than grant approval (U.S. Food and Drug Administration, 2022).

The European Union separates scientific assessment from the final legal decision. Under the centralized procedure, the European Medicines Agency (EMA) coordinates the assessment, and its Committee for Medicinal Products for Human Use issues an opinion.

The European Commission then grants the authorization. The standard scientific assessment takes up to 210 active days. The clock stops while the applicant answers questions, so 210 days is not the total elapsed time. The Commission's decision should follow within 67 days of the opinion. One centralized authorization provides access to the EU market, while pricing and public reimbursement remain separate decisions. This system shares scientific assessment across countries before national payers decide what to purchase (European Commission, 2026, European Medicines Agency, 2024).

Japan similarly separates scientific review from the ministerial approval decision. The Pharmaceuticals and Medical Devices Agency (PMDA) evaluates the application and supporting evidence, with final authorization granted by the Ministry of Health, Labour and Welfare (MHLW). Its stated total-review targets are twelve months for standard new drugs and nine months for priority products. These targets include the time taken by both the authority and the applicant, unlike the EU's active-review clock (Pharmaceuticals and Medical Devices Agency, 2023). Public insurance listing follows a separate process. Across the three systems, preparing the submission, answering questions and securing authorization are therefore distinct margins on which costs and waiting time can arise.

The manufacturer's decision to apply comes before any of these review clocks. PMDA's October 2024 account of Japan's drug lag illustrates its importance. Among 143 medicines approved in Europe or the United States in 2016–2020 but still unapproved in Japan at the end of 2022, 86 had no identified Japanese development activity by March 2023. That is 60.1% of this unapproved group (Pharmaceuticals and Medical Devices Agency, 2024). A faster review target affects a submitted application, whereas a firm deciding whether to develop and file in a market also considers expected demand, prices and local evidence costs. This distinction connects the approval process to the launch incentives documented by Kyle (2007) and Cockburn, Lanjouw, and Schankerman (2016).

Commercial negotiations can also reverse access after authorization. In April 2021, news reporting described bluebird bio's withdrawal of Zynteglo from Germany after reimbursement negotiations failed. The company's subsequent annual report attributed its European exit to prolonged payer negotiations and difficulties securing market access. EMA records confirm that the EU authorization, first granted in May 2019, was withdrawn at the company's request for commercial reasons in March 2022 (Liu, 2021, bluebird bio, Inc., 2022, European Medicines Agency, 2022). This case makes the economic distinction concrete. Regulatory permission creates the opportunity to supply a medicine, while a price acceptable to both the supplier and payer determines whether that opportunity is taken up.

Firms can pursue faster regulatory access and a particular pricing strategy together.

Reuters reported in September 2025 that Bristol Myers Squibb planned to launch Cobenfy in the United Kingdom at the US list price. Its own announcement specified an intended application through the UK's International Recognition Procedure, using the prior FDA authorization, while seeking engagement with the NHS and its reimbursement assessor (Reuters, 2025, Bristol Myers Squibb, 2025). This was an announced application and launch strategy. It illustrates why a reliance route and public coverage are separate choices. International reference pricing can make the price accepted in one country matter for revenues elsewhere, strengthening manufacturers' incentives to choose both launch sequence and price carefully (Maini and Pammolli, 2023).

2.2 What constitutes a reliance arrangement?

Regulatory reliance allows a domestic authority to use an assessment completed by a trusted foreign regulator when reaching its own decision. The domestic authority retains responsibility for authorization. An international survey documents reliance in both well-resourced and more resource-constrained regulatory systems (Doerr, Valentin, Nakashima, Orphanos, Santos, Balkamos, and Saint-Raymond, 2021). The common objective is to avoid repeating scientific work that can be used from elsewhere (World Health Organization, 2021).

Three procedures differ in how much work remains domestic. Abridged review uses foreign findings and retains selected domestic assessment. Verification checks whether the submitted medicine matches the approved foreign product and satisfies the route's conditions. Recognition gives a foreign decision formal effect under domestic law without a further scientific assessment. WHO guidance distinguishes these procedures according to the product, available evidence and domestic regulatory setting (World Health Organization, 2021). We record both the procedure and the work it requires.

A foreign approval and its scientific reports provide different things. The approval establishes that a regulator authorized the product. The reports explain how the regulator assessed its quality, safety and efficacy. A receiving authority may need these reports to use the foreign work. South Africa's abridged-review framework illustrates requirements for matching applications and unredacted assessment reports (Keyter, Salek, McAuslane, Banoo, Azatyan, and Walker, 2020). Authorities relying on European assessments also differ in the documents they request (Poulard, Ausborn, Allchurch, Palmi, Ganan, Joos, Deavin, Beauchesne, Shah, Krishnan, and Askri, 2025). Access to confidential reports can depend on manufacturer consent and permission to exchange information between regulators (World Health Organization, 2021). Our legal coding therefore separates approval

credentials, report access and sharing permissions.

Cooperation can also change how the authorization decision is organized. Under unilateral reliance, an authority uses foreign work without a reciprocal commitment. Joint review involves regulators sharing assessment activities (Doerr et al., 2021, World Health Organization, 2021). In the European Union, mutual recognition extends an existing national authorization to other participating countries. The centralized procedure instead uses a common scientific assessment followed by a European Commission authorization valid throughout the European Union (European Medicines Agency, 2024). These are distinct institutional arrangements, and we code them separately.

The treatment calendar combines three documented events. A national event identifies a domestic reliance route. A European event identifies entry into EU/EEA shared authorization. A WHO event identifies participation in collaborative registration for prequalified medicines. The WHO programme applies to its qualifying products, while national and European arrangements have their own eligibility rules. In the expanded comparison, treatment begins at the earliest of these events recorded for a country. The national-route comparison rebuilds the calendar using national routes alone. Each arrangement makes foreign or jointly produced regulatory work available for domestic authorization. Their product coverage, legal authority and implementation differ, and the pooled comparison summarizes this documented institutional availability. Product applications and funding decisions are subsequent choices.

The scope of each arrangement is important for interpreting this treatment. Some procedures cover particular medicines, manufacturing inspections or changes to an existing product (World Health Organization, 2021). We record these limits and distinguish them from routes for marketing authorization. Domestic authorities can also retain checks relevant to local populations, disease patterns and clinical practice (Mukonzo, Ndagije, Sabblah, Mathenge, Price, and Grasela, 2024). The country-level treatment identifies a documented form of regulatory cooperation, and the standardized-medicine analysis establishes which procedures a particular applicant can use.

2.3 Impact of Regulatory Reliance on government spending

Who pays for treatment matters even when the medicine and its clinical benefit are unchanged. A household paying at the point of care must find the money when illness occurs. Public coverage pools this risk across taxpayers or insured contributors, while committing public resources that have other uses. WHO estimates that 2.1 billion people, or 26% of the world's population, faced financial hardship from out-of-pocket healthcare payments

in 2022. This included 1.6 billion people living in poverty or pushed further into it by those payments. Among the poorest population group, approximately three in four faced financial hardship, compared with fewer than one in twenty-five among the richest (World Health Organization, 2025c). The allocation of the healthcare bill therefore bears directly on household consumption, borrowing and exposure to financial risk.

Public insurance changes purchasing decisions as well as financial protection. Evidence from the introduction of Medicare shows a reduction in exposure to large out-of-pocket bills (Finkelstein and McKnight, 2008). Research on Medicaid identifies substantial insurance value (Finkelstein, Hendren, and Luttmer, 2019), while Medicare Part D lowered pharmaceutical prices and increased use among previously uninsured beneficiaries (Duggan and Scott Morton, 2010). Government financing can spread treatment costs and strengthen purchasers' bargaining position. It can also increase treatment purchases and the demand on public budgets. A larger public contribution consequently has implications for both household welfare and fiscal allocation.

Regulatory reliance can affect this division of payments by changing the treatments available for purchase. Usable foreign reports and sharing permissions can reduce repeated work and make an authorization route less costly or faster. Manufacturers then compare the expected return from the destination market with application costs and waiting time. Adapting the market-size logic of Acemoglu and Linn (2004), the model connects this entry decision to the treatments public payers choose to finance. The government share rises when coverage takes over an existing household bill or when newly purchased treatment receives a greater public contribution than existing care. This mechanism operates through entry opportunities and coverage decisions. Appendix A presents the model and proofs.

Prior medicine-import dependence identifies where access to products assessed abroad is particularly relevant. In these countries, reliance can lower a barrier between internationally available medicines and domestic purchasers. Public payers may respond by financing additional treatments or extending coverage, while households may face less pressure to pay directly. The outcome we study is the government share of total healthcare expenditure. Spending decompositions show whether changes in this share accompany greater public spending, changes in household payments or changes in total purchases. Household surveys then examine borrowing and financial hardship.

Main hypothesis. Following a documented reliance arrangement, the government share of healthcare expenditure increases more in countries with greater prior medicine-import dependence than in otherwise comparable countries that adopt later.

3 Entry, credible assessments and public coverage

To understand why drug reliance regulations may cause more public funding, we extend the profit-incentive logic of Acemoglu and Linn (2004) from innovation to domestic entry by medicines already available abroad. We add a certification channel, motivated by Atal, Cuesta, and Sæthre (2026), and a public-coverage decision informed by the mixed public–private provision framework of Epple and Romano (1996). The model distinguishes two consequences of reliance: changing suppliers' incentives to enter and changing the willingness to finance treatment publicly. Prices and other healthcare expenditure are held fixed.

Entry and credible assessments. Country j has M_j potential foreign medicines. Reliance changes the approval regime from $r = 0$ to $r = 1$. A supplier earns nonnegative operating value $\Pi_j(q_r)$, where q_r is the perceived probability that treatment meets the relevant quality standard. Operating value is nondecreasing in q_r because greater confidence can increase treatment demand. The supplier draws an application cost c from a continuous distribution F_j. Authorization prospects are held fixed and normalized to one. With filing cost f_r, approval delay d_r and discount rate $\rho > 0$, the entry cutoff and expected number of entrants are

$$c_r^* = e^{-\rho d_r}\Pi_j(q_r) - f_r, \qquad N_r = M_j F_j(c_r^*). \tag{3.1}$$

The distribution is zero below its nonnegative support. A supplier enters when $c < c_r^*$. Usable foreign reports and sharing permissions can reduce filing costs or waiting times by replacing repeated assessment.

Foreign assessments may also convey information to clinicians, patients and public payers. Let $q_0 \in (0, 1)$ be their prior probability of acceptable quality. A newly informative favorable assessment with likelihood ratio $\ell > 1$ gives

$$q_1 = \frac{\ell q_0}{1 - q_0 + \ell q_0} > q_0.$$

The likelihood ratio captures the information conveyed by a trusted reference authority's assessment. If that evidence is already incorporated in beliefs, reliance leaves confidence unchanged.

Proposition 3.1 (Lower entry barriers)**.** *If reliance weakly lowers filing costs and delays, preserves authorization prospects and gives $q_1 \geq q_0$, expected entry weakly in-*

creases. Entry increases strictly when the improved cutoff crosses a positive mass of supplier costs. Holding the response per medicine fixed, a larger potential foreign-medicine pool produces a larger absolute entry response.

The result follows from $c_1^* \geq c_0^*$ and the monotonicity of F_j. Reliance can therefore make previously unprofitable destinations worth supplying. This motivates prior medicine-import dependence as an empirical measure of exposure, although it does not identify the potential foreign-medicine pool directly.

Confidence, private use and public coverage. Following entry and initial private use, let $A_r > 0$ denote the eligible treatment bill and n_r the visibility of treatment to patients and clinicians. The government chooses the fraction $s \in [0, 1]$ financed publicly:

$$\max_{\substack{0 \leq s \leq 1 \\ sA_r \leq K_j}} A_r \left[(a_j q_r + b_j n_r - \lambda_j) s - \frac{\kappa_j}{2} s^2 \right]. \tag{3.2}$$

Here $a_j, b_j \geq 0$ capture the value placed on credible treatment and demand for coverage, $\lambda_j \geq 0$ is the fiscal cost of public funding, $\kappa_j > 0$ captures diminishing net benefits, and $K_j \geq 0$ is the available budget. The term $b_j n_r$ represents the proposed pressure for public coverage following visible use in private practice. The unique solution is

$$s_r^* = \min \left\{ 1, \frac{K_j}{A_r}, \max \left[0, \frac{a_j q_r + b_j n_r - \lambda_j}{\kappa_j} \right] \right\}. \tag{3.3}$$

Households pay the remaining eligible bill, $(1 - s_r^*) A_r$.

Proposition 3.2 (Credible assessments and public financing)**.** *If reliance conveys favorable informative evidence, confidence increases. If private visibility does not fall and the budget is nonbinding in both regimes, public coverage weakly increases. Write* $\Delta s = s_1^* - s_0^*$ *and* $\Delta A = A_1 - A_0 \geq 0$*. With other healthcare expenditure fixed, the government financing share rises precisely when*

$$A_0 \Delta s + (s_1^* - S_0) \Delta A > 0, \tag{3.4}$$

where S_0 *is the initial government share of total healthcare expenditure. Household payments fall precisely when* $A_0 \Delta s > (1 - s_1^*) \Delta A$*.*

Public coverage can thus absorb existing household bills, while treatment expansion can increase expenditure by both purchasers. A binding budget can limit the coverage response even when confidence and demand increase.

Economic motivations behind reliance laws. Governments anticipate these consequences when choosing their regulatory arrangements. Let V_r denote optimized coverage value plus the value of treatment availability outside public coverage. A government adopts reliance when

$$V_1 - V_0 + R_j \geq C_j + \omega_j L_j,$$

where R_j denotes regulatory resource savings, C_j implementation costs and $\omega_j L_j$ politically weighted losses to domestic producers. Following the political-economy perspective of Maggi and Ossa (2023), legal choices can therefore reflect access benefits, fiscal constraints and producer interests. We posit that reliance can improve household financial protection when lower entry barriers and credible assessments are accompanied by public coverage that absorbs existing household payments.

4 Data and methodology

4.1 Primary data on regulatory texts

We screen 250 countries and areas. Textual analysis requires a country-specific passage with traceable wording and an identifiable source in English or a documented translation. The resulting sample contains 439 passages from 134 jurisdictions. The remaining 116 jurisdictions remain in the geographic inventory but contribute no retained country document to the textual analysis. The sample includes legislation and guidance alongside historical rules and contextual material. A jurisdiction's inclusion therefore means that we have a relevant document to analyse. It does not necessarily mean that the jurisdiction had an operative reliance programme during the study period. We establish treatment status and adoption dates separately using dated qualifying national arrangements and WHO and EU/EEA participation histories.

The wording analysis uses 439 national passages from all 134 represented jurisdictions. Of these, 313 are English-language source passages and 126 are translated into English. We retain the original wording alongside each translation. The nine shared-system passages are analyzed separately from national country documents.

We use the passages to identify the conditions facing applicants. The legal-feature analysis codes 89 national-rule profiles, recording accepted foreign authorities, product eligibility, report requirements and remaining domestic assessment. The common-medicine exercise combines these profiles with additional route-specific evidence to assess the same application in 94 country cases. These analyses describe legal requirements. Table 1

instead reports the economic regression samples, which require a qualifying event date and complete expenditure, exposure and control histories. Those requirements yield 69 treated jurisdictions for the main DiD and 30 for the national-route DiD.

For each route, we record the accepted foreign authorities, eligible products, required reports, sharing permissions and remaining domestic assessment. We also record the basis for its date, distinguishing an operative provision, an enactment, a dated observation of operation and an amendment. Provisions are carried forward until an identified change. The dated legal inventory contains 49 jurisdictions by 2025, including 41 national routes. Adding EU/EEA and WHO participation histories gives a chronology for 132 jurisdictions. Figure 1 displays the 134-country corpus sample, with blank cells where no dated positive evidence is available. Linking documented histories to complete economic outcome windows gives 69 treated jurisdictions in the expanded financing comparison and 30 in the national-route comparison. The legal-profile and financing samples serve distinct purposes. The financing samples depend on documented event dates and complete outcome, exposure and control histories. We corroborate pathway coding against Poulard et al. (2025) and use WHO definitions to distinguish recognition and abridged assessment (World Health Organization, 2021).

Textual analysis describes how countries write these requirements. Following Gentzkow, Kelly, and Taddy (2019), we pool usable passages into one document for each of the 134 countries. We remove country names and common boilerplate, combine grammatical variants and harmonize spelling. We retain legal negations and modal terms such as no, not, may and shall. TF–IDF gives less weight to words common across documents, and cosine similarity compares countries' vocabulary. Latent Dirichlet allocation groups words that recur together into themes. We choose between two and five themes using a coherence measure of how consistently their words occur together. We also repeat the analysis with equal word mass across countries and with national-rule and language subsets. The pooled documents include preserved versions and later updates. We retain their source dates and use the separate 2000–2025 calendar to date treatment.

4.2 Secondary data on spending and financial strain

The economic data show how treatment purchases and their financing change around the institutional events. We link the legal corpus to UN Comtrade pharmaceutical imports and World Bank/WHO health accounts (United Nations Statistics Division, 2026, World Bank, 2026). Both sources contain observations for 193 jurisdictions. Annual source data cover 2000–2024. The expanded comparison uses events with three complete subsequent years

TABLE 1
Economic estimation samples

Estimation sample	Treated	All countries
Main DiD [Table 3, Panel A]	69	74
National-route DiD [Table 3, Panels A–B]	30	37
National-route robustness [Table 7]	17*	33*
Medicine-import DiD [Table 8, Panel C]	20*	35*
Household-expenditure DiD [Table 8, Panel C]	20*	37*
Findex medical borrowing [Table 4, Panel A]	10*	16*
WHO financial protection [Table 4, Panel B]	12*	22*

This table reports treated and total country counts for each economic outcome. The main DiD combines national routes, WHO collaborative-registration participation and shared European authorization. The national-route DiD uses national arrangements alone. Both retain the three-year pre-event financing-trend control. Complete outcome windows, prior import exposure and controls yield 69 treated jurisdictions across 74 countries and 30 national-route jurisdictions across 37 countries. Asterisks mark supplementary samples limited by the availability of the required outcomes and covariates.

and observed outcomes through 2023. Available observations from 1995–1999 supply pre-event histories for early arrangements.

The import and health-account data answer different parts of our question. Packaged-medicine imports, classified as HS3004, measure expenditure on imported pharmaceuticals. Imports per person describe purchases, while imports relative to GDP measure prior dependence on foreign medicines. National health accounts provide government, household and total healthcare expenditure, along with the share paid by each financing source. Our main outcome is the government share of all healthcare spending. These are annual country-level measures. We use current US dollars for the baseline expenditure comparisons and examine purchasing-power and inflation adjustments separately.

Household surveys measure the financial pressure associated with paying for care. Our reported survey comparisons use published national estimates from Global Findex and WHO financial-protection surveys. Findex records borrowing for medical expenses in 2014, 2017, 2021 and 2024 (World Bank, 2025). WHO records financial hardship and impoverishing expenditure under its financial-protection definitions (World Health Organization, 2025a). The wider collection includes Afrobarometer measures of going without medicines or treatment, HEFPI measures of catastrophic and impoverishing spending, and EHIS, EU-SILC, Australian and New Zealand affordability histories (Afrobarometer, 2026, World Bank, 2022). We analyze sources separately and retain their stated populations and definitions. Table 2, Panel C summarizes their coverage.

TABLE 2
Summary statistics and qualifying treatment events

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$)	331.7	315.6	69	305.3	308.8	312
Real GDP per person (constant US$)	18846.3	18377.1	69	16708.1	17042.1	312
Government share of health spending (%)	55.9	16.8	69	50.3	14.9	312
Medicine imports/GDP (%)	0.5	0.3	67	0.6	0.5	310

Panel B. Qualifying events in the financing samples

Qualifying event	Expanded sample	National-route sample
National reliance route	25	30
WHO collaborative-registration participation	31	—
EU/EEA shared authorization	13	—
Total treated jurisdictions	69	30

Panel C. Secondary household-survey sources

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

This table reports pre-event country characteristics, dated national arrangements and household-survey coverage. Panel A uses pre-reform GDP weights from the expanded financing comparison and measures characteristics in year $g-1$. Its 381 country–event observations comprise 69 treated and 312 comparison observations across 74 countries. Comparison countries can recur across event groups. Counts reflect availability for each characteristic. Panel B classifies the qualifying events used in the current financing samples. The expanded calendar uses the earliest qualifying national, WHO or EU/EEA event. One jurisdiction has national and WHO events in the same year and is counted under national routes. The national-route calendar is rebuilt independently, excluding WHO and EU/EEA events. Counts are mutually exclusive within each column. Panel C describes each survey's observed coverage and household measures. Findex covers adults aged 15 and above. Afrobarometer covers adult respondents and their families. The New Zealand measure covers all adults.

4.3 Empirical design and comparison methods

We define treatment at country level using the earliest qualifying event in the institutional calendar. A country can first qualify through a national reliance route, WHO collaborative-registration participation or EU/EEA shared authorization. Each event retains its product scope and documented dating basis. The expanded national calendar includes formal foreign-review pilots, conditional or provisional routes, biologic-specific provisions and a documented verification-route expansion. These dates identify the recorded qualifying arrangement within its stated scope. We record whether the date comes from an operative rule, guidance or a participation record. The same country can have more than one type of arrangement, but its earliest qualifying event sets the qualifying treatment date.

The expanded sample contains 69 treated jurisdictions and 74 countries. Qualifying events occur from 2004 to 2020, with outcome windows extending through 2023. The 381 country–event observations comprise 69 treated and 312 comparison observations. A comparison country can appear in more than one event group and can later become treated. Rebuilding the treatment calendar using national routes alone gives 30 treated jurisdictions and 37 countries. National event dates and eligible later-adopter comparisons can differ from those in the expanded calendar. Both comparisons retain the original three-year pre-event financing-trend control.

For an event in year g, we compare the treated countries with countries whose own event occurs after the full outcome window. We measure the outcome change as

$$\Delta Y_{cg} = \frac{1}{3}\sum_{h=1}^{3} Y_{c,g+h} - Y_{c,g-1}, \tag{4.1}$$

which compares the average of the first three full post-event years with the last full pre-event year. The event year is excluded. Expenditure enters in logs and financing shares in percentage points. A comparison country's date must fall after $g+3$, and each event group must contain at least two complete comparison countries. Following Callaway and Sant'Anna (2021), countries serve as comparisons before their own qualifying event.

We first estimate the average difference between treated and comparison countries,

$$\Delta Y_{cg} = \alpha_g + \beta T_{cg} + \varepsilon_{cg}, \tag{4.2}$$

where T_{cg} equals one for countries with the event in year g and zero for their later-treated comparisons. The date-group effect α_g accounts for the common change over that comparison window. The coefficient β measures the difference in outcome changes between

the two groups.

Our main question is whether this financing difference is larger where imported medicines are more important. We estimate

$$\Delta Y_{cg} = \alpha_g + \beta T_{cg} + \theta(T_{cg} Z_{cg}) + \pi Z_{cg} + X'_{cg}\delta + u_{cg}, \tag{4.3}$$

where Z_{cg} measures prior medicine-import dependence. We average the log HS3004-import-to-GDP ratio over years $g-4$ to $g-2$ and express it on a fixed standard-deviation scale. One unit corresponds to approximately a 2.25-fold difference in that ratio. The interaction coefficient θ is our primary estimand. It measures how the treated–comparison financing difference changes with prior import dependence. In this specification, β measures that difference at the fixed exposure-reference mean, where $Z_{cg} = 0$. We retain both main effects. The controls X_{cg} include prior income, the pre-event outcome and its earlier trend.

Identification requires conditional parallel trends. In the absence of the qualifying arrangement, treated and eligible later-adopting countries must have comparable financing changes conditional on these pre-event characteristics and import dependence. The comparison also requires no anticipatory outcome response within the untreated window and no differential spillovers that alter that counterfactual. Pre-event comparisons, alternative dates and comparison-group checks assess this identifying structure. The pooled interaction summarizes differential financing responses across the included arrangements and GDP weights.

We then ask how the initial financing environment changes this relationship. Following the pre-reform insurance comparisons of Finkelstein (2007), we add prior household financing and income as standardized moderators, retaining their main effects. Separate regressions add demographic, fiscal, general-trade, pandemic and macroeconomic measures. Earlier outcome changes and alternative event dates provide timing checks on the conditional parallel-trends comparison.

Survey regressions compare observed waves, requiring pre-event fieldwork to end before the earliest documented treatment date and post-event recall to begin after the latest date and implementation lag. Findex uses national reliance events, while WHO financial-protection regressions use collaborative-registration participation for prequalified medicines. Both control for prior income, the baseline outcome and survey-pair effects. Findex adjusts for pandemic recall exposure interacted with prior public financing, while WHO adds prior external health financing. Survey-linked financing and borrowing use identical observations, controls and weights. Financing regressions use pre-event

real GDP weights, normalized to equal treated and comparison weight totals within each event group. Alternatives cap GDP weights at the treated-sample 95th percentile or weight treated countries equally. Country differencing removes time-invariant effects. Expanded financing and survey regressions use country-cluster CR2 standard errors and Satterthwaite tests (Pustejovsky and Tipton, 2018), with wild cluster bootstrap checks (MacKinnon and Webb, 2018). Supplementary national-route regressions use CR1. The 2023 legal-profile cross-section controls for income, population, age composition and region and uses HC3 standard errors.

5 Findings

We begin by mapping the regulatory corpus through its wording and the requirements facing the same medicine. These analyses characterize the forms of reliance and the procedures available to suppliers. We then compare the public-financing response across countries with different prior medicine-import dependence. Subsequent tests examine household financial strain, the initial payer mix and alternative explanations. Finally, we decompose spending on the main sample to identify the government, household and other-financing contributions.

5.1 What foreign approvals require and what they offer

Following the standardized-case approach of Djankov et al. (2002, 2008), we apply the same hypothetical medicine and dossier across countries to map the types of reliance, documentary requirements and approval routes in our legal corpus.

Our characterization shows that reliance is commonly restricted to specified products or procedures and accompanied by continuing domestic requirements. Among the 89 coded national-route jurisdictions, 63 (70.8%) specify product or procedural scope, 52 (58.4%) address foreign reports or sharing permissions, and 50 (56.2%) retain domestic decision or further-review powers. Product or dossier matching appears in 40 profiles (44.9%), additional local evidence or assessment in 30 (33.7%), and a review target or deadline in 35 (39.3%) (Figure 2, Panel B). These nonexclusive categories describe documented provisions within the selected national profiles. They show that the availability of a reliance route combines foreign regulatory work with rules about which products qualify and what domestic assessment remains.

Access to foreign information and domestic decision rights frequently appear together. Of the 52 profiles addressing reports or sharing permissions, 31 (59.6%) also retain do-

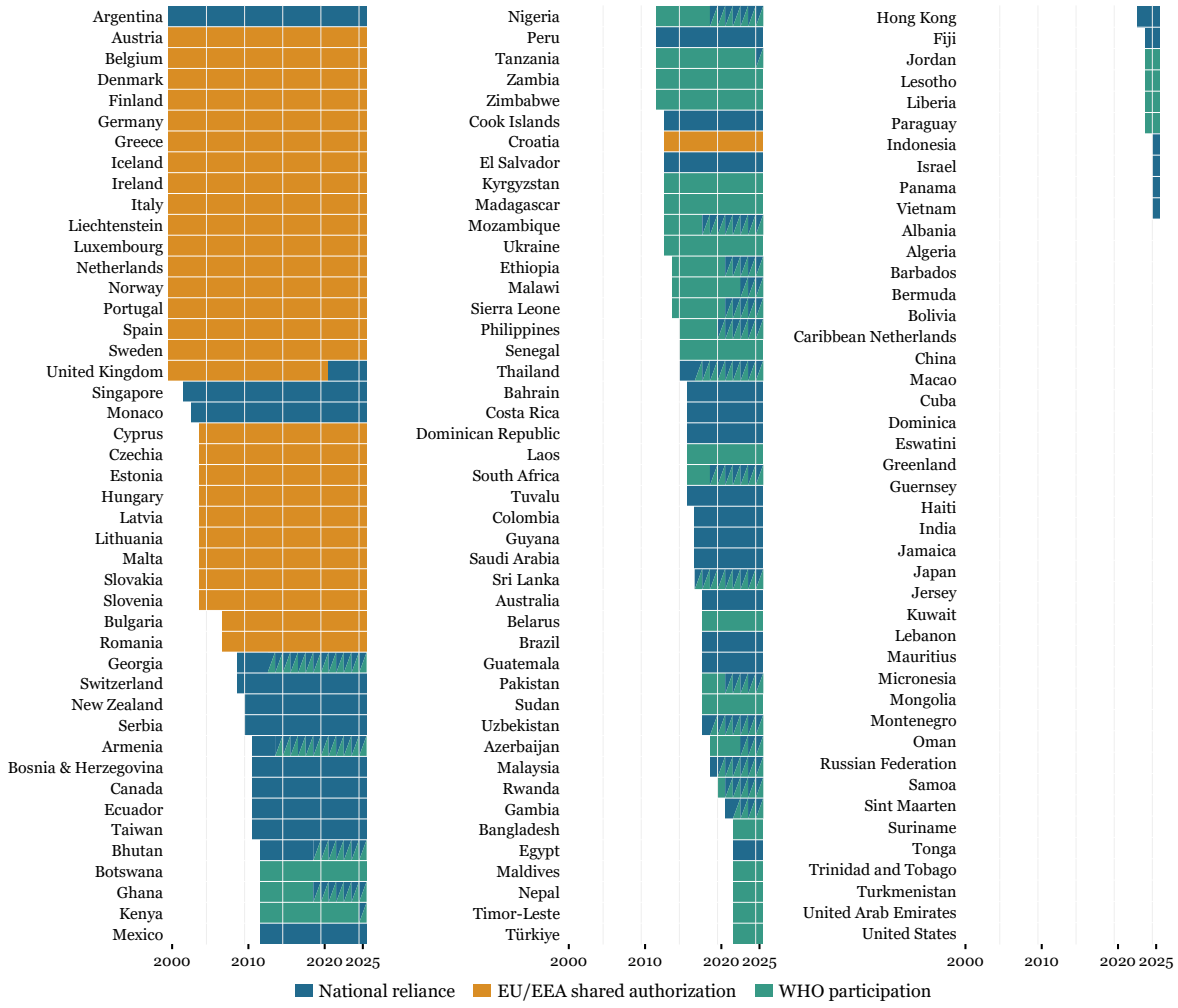


Figure 1: The international spread of reliance

This figure shows reliance histories across all 134 corpus jurisdictions during 2000–2025. National reliance is blue, EU/EEA authorization gold, and WHO participation green. Overlap uses diagonally split cells. (World Health Organization, 2025b).

mestic decision or further-review powers. This overlap characterizes reliance as a way to use foreign work within a domestic authorization decision. It provides evidence that information sharing and continued local oversight are complementary features of many documented arrangements.

The type of information requested creates another important distinction. Thirteen profiles (14.6% of the 89) expressly address complete or nonpublic reports, compared with 52 addressing reports or permissions more broadly. The broader report category therefore cannot be read as a uniform requirement for confidential scientific assessments. A foreign approval, a public summary and a full assessment report supply different documentary

inputs. This distinction explains why our common-medicine comparison varies report completeness and sharing permission separately from the number of foreign approvals.

The text analysis provides a complementary description of the language surrounding these requirements. A latent Dirichlet allocation model groups 439 passages, pooled into 134 country documents, by words that recur together. Coherence selects three themes. Registration and supporting information is dominant in 66 documents (49.3%), authorization and recognition in 46 (34.3%), and assessment reports and reliance in 22 (16.4%). Each document is assigned to its largest-weight theme for this display and can discuss several themes (Figure 2, Panel A). These are shares of country documents by language emphasis. The coded provisions above identify the substantive legal conditions within national routes.

To connect the language patterns to a specific institutional feature, we test whether report-oriented wording predicts the separately coded provisions concerning complete or nonpublic reports. The regression is

$$R_c = a + b(10s_c) + W_c'\gamma + \varepsilon_c, \tag{5.1}$$

where R_c equals 100 when a profile contains that report wording and zero otherwise, and s_c is the assessment-and-review topic share between zero and one. The controls W_c include income, region, text length and source count. A ten-percentage-point higher topic share is associated with a 6.9-percentage-point higher probability of documented report wording. We then remove the entire source used to code the requirement and use the topic share alone in a separate regression. The association is 3.9 points in the remaining documents. Report-oriented language thus corresponds to a separately coded feature of the reliance rules.

Applying these conditions to the common medicine in 94 country cases shows which requirements change an applicant's options. We vary foreign approvals, complete reports and sharing permissions while holding the medicine, manufacturer and dossier constant. Complete reports and permissions satisfy an applicable complete-report condition in nine cases, and 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. Seven of the 13 profiles with complete or nonpublic-report wording overlap with the nine complete-content conditions. Other profiles contain conditional requirements, alternative-information arrangements or a need for further implementing detail. The fixed medicine identifies which conditions matter for the supplier and which alternative routes remain available.

The applicant comparison identifies available procedures. We next ask what an additional foreign approval offers in terms of the published time to review. For five matched route menus, we estimate

$$\log D_{cr} = \alpha_c + \delta A_{cr} + u_{cr}, \tag{5.2}$$

where D_{cr} is the published target for route r in country c, A_{cr} identifies the route requiring one additional qualifying foreign approval, and α_c is a country fixed effect. We hold the medicine and other eligibility conditions satisfied. The coefficient is -0.628 log points, corresponding to a 46.7% shorter published target. The paired targets are 120 versus 70 net working days in Israel, 45 versus 30 working days in the Philippines, 60 versus 30 working days in Saudi Arabia, 180 versus 60 working days in Singapore, and 180 versus 120 stated days in Taiwan. Omitting each jurisdiction in turn gives reductions between 40.0% and 49.5%. These procedures give an additional qualifying foreign credential a substantial written time advantage.

We extend the timing display by screening all 94 country cases for a published target relevant to the same hypothetical product, which we call Medicine H. It is an originator, non-emergency, non-orphan, non-first-in-class small-molecule medicine for adults, manufactured at the same US site with an identical formulation and full dossier. Complete reports and permissions are available. For this timing display, FDA approval and US marketing are 18 months old, and EC and Japanese approvals are six months old. Other published route conditions are held satisfied. Panel C reports targets for 32 national jurisdictions and the EU centralized scientific-review benchmark, ordered from longest to shortest on an approximate day scale. Assessment-only stages are marked separately. The timing chart includes only countries with a published numerical review target.

The corpus therefore identifies recurring conditions governing access to foreign work, while the common medicine shows how those conditions affect available procedures and published review targets. Figure 1 places all 134 corpus jurisdictions on the institutional timeline. We next link the legal corpus to healthcare accounts and ask whether reliance is followed by a larger public-financing response where countries depend more on imported medicines.

5.2 Reliance arrangements and public financing

Having mapped the institutional arrangements, we ask whether they are followed by a larger shift toward government financing in more import-dependent countries. We estimate equation (4.3), relating the percentage-point change in government share to treatment, prior import dependence and their interaction. The expanded comparison pools

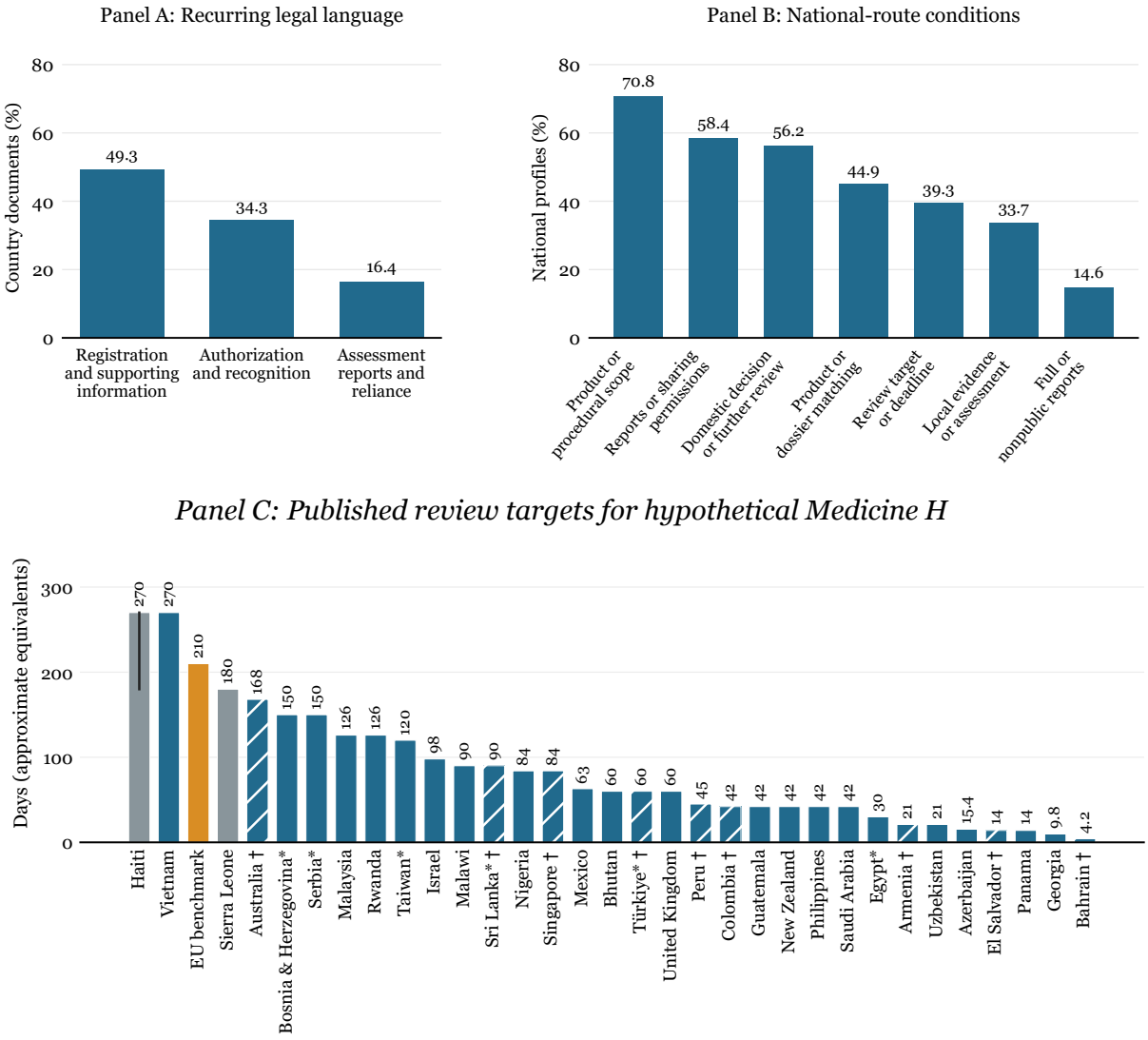


Figure 2: Legal wording, documentary requirements and written review targets

This figure shows wording, documentary conditions and published review targets. Panel A groups 439 passages pooled into 134 country documents by dominant LDA theme. Sources include rules, guidance, drafts and contextual material in English or research translation. Panel B reports nonexclusive conditions in 89 national-route profiles. Labels in A–B are percentages. Panel C covers 32 national targets and an EU benchmark for the same hypothetical adult small-molecule Medicine H, ordered longest to shortest. Working days are multiplied by 7/5 and months by 30, without holiday adjustments. Asterisks mark unspecified day conventions retained as stated. Hatching and † mark assessment stages excluding other registration steps. Grey bars show ordinary registration in Haiti (180–270 approximate days) and Sierra Leone (180 days). Gold denotes the EU's initial scientific assessment, excluding applicant clock stops and the later Commission decision.

national routes, WHO participation and shared European authorization as documented access to foreign or joint regulatory work, with 69 treated jurisdictions and 74 countries overall. With pre-reform real GDP weights, a roughly 2.25-fold difference in prior medicine imports relative to GDP is associated with a 2.42-percentage-point larger increase in government share. Capping GDP weights gives 2.44 points (Table 3, Panel A). The financing shift is therefore larger where imported medicines are more important before the arrangement.

The expanded treatment includes different forms of regulatory cooperation. We next ask whether the financing pattern also appears when treatment is defined by a domestic reliance route alone. Excluding WHO participation and shared European authorization as qualifying events gives 30 treated jurisdictions. The GDP-weighted coefficient is 4.28 percentage points, compared with 2.42 points in the broader sample. Equal country weights give 3.08 points in the pooled model and 4.26 points when treatment and exposure terms differ across reform-date groups (Table 3, Panel B and Figure 3). The national-route comparison shows a positive financing association under both GDP and equal-country weights. Its event dates and eligible comparison groups are rebuilt under the national definition, so the coefficient contrast also reflects a different institutional comparison.

The three-year average summarizes the financing change but leaves its timing open. We therefore estimate the same exposure interaction separately for each of the first three full post-event years. GDP-weighted coefficients are 1.52, 2.82 and 2.93 percentage points. Capped GDP weights give 1.56, 2.84 and 2.91 points (Figure 3, Panel B). Under both weighting schemes, the estimated financing difference is larger after the first year. We next examine whether the financing pattern is accompanied by lower household financial strain.

5.3 Medical borrowing and household financial hardship

As a robustness check on the household implications of the financing result, we examine whether more import-dependent countries also show larger declines in independently measured financial strain. We start with medical borrowing in Global Findex and use observed survey-wave changes in equation (4.3). The baseline exposure interaction is -3.21 percentage points. Allowing pandemic responses to differ with the pre-reform public-financing share gives -5.23 points across ten treated jurisdictions and sixteen countries (Table 4, Panel A). This provides evidence of a larger decline in medical borrowing among more import-dependent countries after accounting for differences in pandemic financing pressures.

TABLE 3
Public-financing responses in expanded reliance samples

	Panel A: GDP weights			*Panel B: Equal-country weights*			
Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Route sample	Expanded			National		Expanded	
Weights	GDP	Capped GDP	GDP	Equal	Equal	Equal	Equal
Specification	Pooled	Pooled	Pooled	Pooled	Date-group	Pooled	Date-group
Reliance × prior import exposure	2.422*	2.437**	4.278**	3.083***	4.260***	0.667	0.879
	(0.936)	(0.789)	(0.959)	(0.606)	(1.270)	(0.908)	(0.937)
Documented reliance arrangement	1.618*	1.569**	2.223	1.236		1.399*	
	(0.693)	(0.627)	(1.087)	(1.005)		(0.805)	
Prior import exposure	-1.594	-1.665*	-1.994**	-1.691**		-0.653	
	(1.044)	(0.789)	(0.693)	(0.490)		(0.608)	
Pre-reform log real GDP per person	0.852*	0.815*	0.108	0.302	0.199	1.050**	1.323**
	(0.406)	(0.397)	(0.605)	(0.492)	(0.645)	(0.490)	(0.493)
Pre-reform government-financing share	-0.064*	-0.065*	-0.009	-0.031	-0.023	-0.097**	-0.101***
	(0.030)	(0.032)	(0.042)	(0.040)	(0.060)	(0.036)	(0.036)
Earlier government-financing trend	0.121	0.108	-0.168	-0.021	-0.206	-0.016	-0.004
	(0.240)	(0.234)	(0.304)	(0.299)	(0.368)	(0.226)	(0.243)
Country FE (differenced)	X	X	X	X	X	X	X
Date-group FE	X	X	X	X	X	X	X
Date-group treatment/exposure terms	—	—	—	—	X	—	X
Last observed outcome year	2023	2023	2023	2023	2023	2023	2023
Treated jurisdictions	69	69	30	30	30	69	69
Countries	74	74	37	37	37	74	74
Observations	381	381	221	221	221	381	381
R^2	0.246	0.231	0.357	0.233	0.374	0.141	0.233

This table reports financing responses under GDP and equal-country weights. The dependent variable is Δ government share of healthcare expenditure, in percentage points, averaged over $g+1$–$g+3$ relative to $g-1$. Exposure is the standardized mean log medicine imports/GDP over $g-4$–$g-2$. One unit represents a 2.25-fold import-dependence difference. Panel A compares GDP, capped-GDP and national-route estimates. GDP is measured in $g-1$ and capped at the treated-sample 95th percentile. Panel B uses equal-country weights. Its date-group specifications allow treatment and exposure terms to differ across event groups. Comparison weight mass equals treated mass within each group. All columns retain prior income, financing level and trend, country differencing and date-group effects. Sources are the legal corpus, UN Comtrade and World Bank/WHO health accounts. Parentheses contain country-cluster CR2 standard errors. Satterthwaite tests determine significance. ***, ** and * denote 1%, 5% and 10% significance.

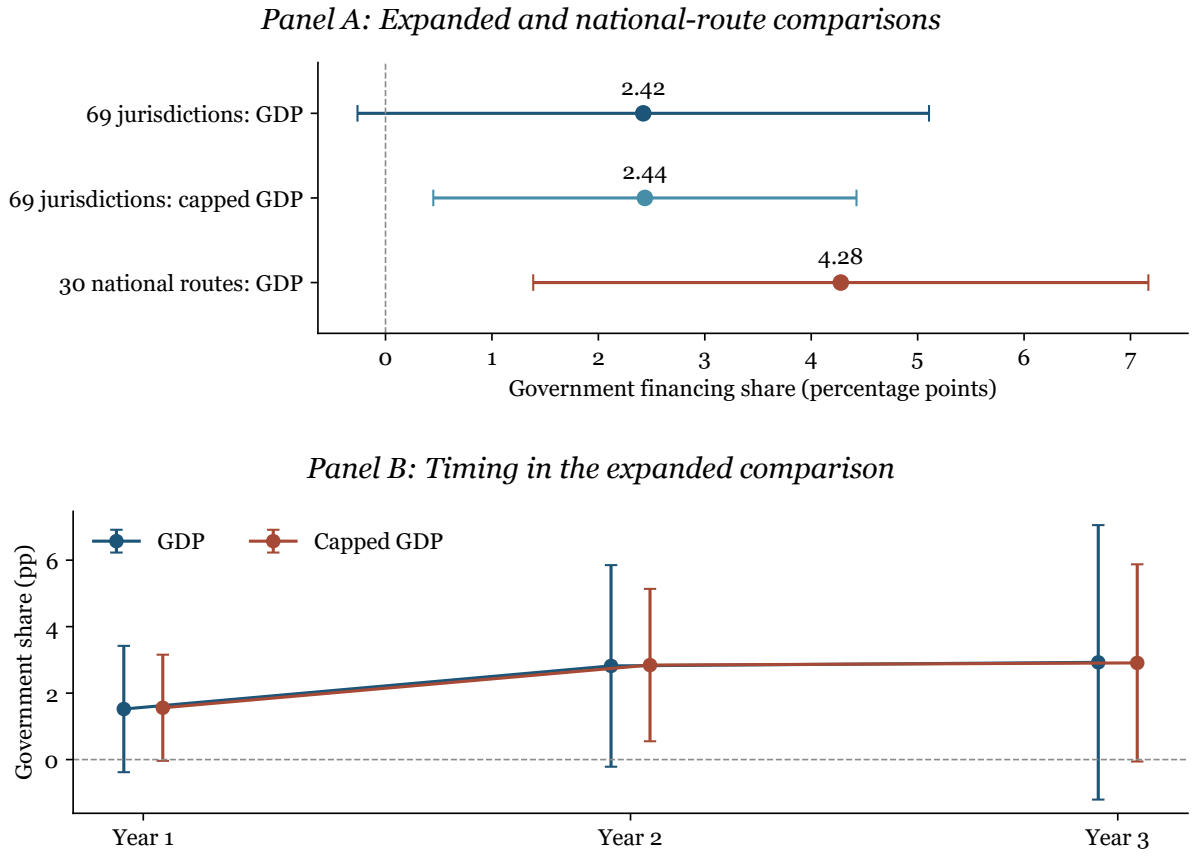


Figure 3: Public-financing responses: expanded and national-route samples

This figure shows public-financing coefficients for prior medicine-import dependence. Panel A reports the 69-jurisdiction GDP-weighted estimate, its capped-GDP counterpart and the 30-jurisdiction national-route estimate: 2.42, 2.44 and 4.28 percentage points. Panel B reports the first three full post-event years for the same expanded sample: 1.52, 2.82 and 2.93 points with GDP weights, and 1.56, 2.84 and 2.91 points with capped weights. Annual coefficients average to the corresponding three-year estimate. One exposure standard deviation represents approximately a 2.25-fold pre-event import-to-GDP difference. GDP is measured before treatment; capped weights use the treated-sample 95th percentile. Bars show 95% country-cluster CR2/Satterthwaite intervals. Outcomes extend through 2023.

Borrowing captures one response to medical bills. We next ask whether the pattern extends to spending that places households in financial hardship. We use WHO financial-protection surveys in the separate setting of collaborative registration for prequalified medicines. Applying the exposure-interaction design and controlling for prior income, the baseline outcome and pre-participation external health financing gives coefficients of -5.61 percentage points for financial hardship and -5.69 points for impoverishing spending across twelve treated jurisdictions and twenty-two countries (Table 4, Panel B). Greater prior import dependence is associated with larger reductions in these measures

of financial pressure.

These tests address complementary household outcomes. The national-route regressions link greater prior import dependence to a larger public-financing response. Findex measures borrowing to meet medical bills, while the WHO surveys measure financial hardship from healthcare spending. The reported survey comparisons show negative exposure gradients in both settings. Together, the results connect the allocation of healthcare payments to household financial protection, as the model's financing hypothesis predicts.

5.4 The financing environment and household payments

The survey results describe household financial pressure but leave open whether existing financing institutions account for the public-financing association. To account for alternative explanations, we examine public purchasing capacity, fiscal conditions and the private payer mix as further robustness checks. Following the pre-reform financing comparisons of Finkelstein (2007), we extend equation (4.3) with pre-event public health spending relative to GDP, government debt, fiscal balance, household payments and voluntary insurance, retaining their main effects and lower-order interactions. Public-spending specifications retain 68 treated jurisdictions, while fiscal specifications retain 69. The exposure coefficient is 2.75 percentage points with prior public spending and 2.70 points with debt and fiscal balance jointly. Adding household payments and voluntary insurance jointly retains 65 treated jurisdictions and gives 3.75 points at the average initial payer mix (Table 5). The corresponding triple interactions assess whether these institutions change the exposure gradient. The larger public-financing response in more import-dependent countries remains after accounting for differences in their initial financing institutions.

The payer-mix result leaves open whether lower household payments reflect lower total expenditure or a smaller household share of the bill. We separate these possibilities in the supplementary national-route expenditure sample. Using equation (4.2), we estimate household spending, total spending and the household-financed fraction on identical observations and weights. The 10.3% decline in household spending corresponds to 1.9% higher total expenditure and an 11.9% decline in the household-financed fraction (Table 6, Panels A–B). Adding prior income and growth gives corresponding changes of -11.1%, 3.2% and -13.9%. The household-payment difference is concentrated in a smaller share paid directly by households.

We then connect these robustness checks to the preceding survey evidence by asking whether financing and borrowing patterns appear on exactly the same country-period observations. We link health accounts to Findex survey dates and use identical observations,

TABLE 4
Regulatory reliance and household financial strain

Panel A: Medical borrowing, national arrangements

Variables	(1)	(2)
Specification	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	X	X
R^2	0.726	0.799

Panel B: Financial protection, WHO collaborative registration

Variables	(1)	(2)
Outcome	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	X	X
R^2	0.762	0.812

This table reports exposure-related changes in household financial strain. The dependent variables are Δ medical borrowing in Panel A and Δ financial hardship or impoverishing spending in Panel B, in percentage points between observed survey waves. The exposure interaction uses the standardized pre-event log medicine-import-to-GDP ratio. Panel A compares baseline and pandemic-adjusted national-route regressions using 38 observations, ten treated jurisdictions and sixteen countries. The adjustment interacts prior public financing with the change in survey-recall overlap with 2020–2021. Panel B uses WHO collaborative-registration participation, 40 observations, twelve treated jurisdictions and twenty-two countries, controlling for prior external health financing. All columns include prior income, the baseline outcome and reform-year/survey-pair effects; country differences remove time-invariant effects. Sources are Global Findex, WHO financial-protection surveys, health accounts, UN Comtrade and institutional histories. Parentheses contain country-cluster CR2 standard errors, with Satterthwaite tests. ***, ** and * denote significance at 1%, 5% and 10%.

TABLE 5
Public purchasing capacity and the financing response

	Panel A: Public financing		*Panel B: Fiscal capacity*		
Variables	(1)	(2)	(3)	(4)	(5)
Specification	GDP	Capped GDP	Debt	Fiscal balance	Both
Reliance × prior import exposure	2.747*	2.738**	2.637**	2.530	2.696**
	(0.967)	(0.918)	(0.773)	(1.280)	(0.858)
Reliance × exposure × Public health spending/GDP	0.263	0.074	—	—	—
	(0.871)	(0.748)			
Reliance × exposure × Public debt/GDP	—	—	-0.992	—	-2.917*
			(0.892)		(1.439)
Reliance × exposure × Fiscal balance/GDP	—	—	—	-0.604	-2.588
				(0.810)	(1.656)
Documented reliance arrangement	2.170**	2.064**	1.600*	1.808*	1.684**
	(0.745)	(0.792)	(0.686)	(0.674)	(0.604)
Prior import exposure	-1.584	-1.648*	-1.876**	-1.495	-1.831**
	(0.997)	(0.822)	(0.692)	(1.035)	(0.611)
Public health spending/GDP	-0.656	-0.327	—	—	—
	(1.335)	(1.225)			
Public debt/GDP	—	—	-0.348	—	0.466
			(0.510)		(0.547)
Fiscal balance/GDP	—	—	—	0.680	1.032
				(0.349)	(0.553)
Pre-reform log real GDP per person	1.340	1.145	0.975*	0.897*	1.064**
	(0.829)	(0.779)	(0.428)	(0.400)	(0.416)
Pre-reform government-financing share	-0.054	-0.059	-0.078**	-0.087**	-0.090**
	(0.040)	(0.039)	(0.027)	(0.027)	(0.027)
Earlier government-financing trend	0.168	0.164	0.157	0.216	0.168
	(0.284)	(0.266)	(0.225)	(0.201)	(0.189)
Country FE (differenced)	X	X	X	X	X
Date-group FE	X	X	X	X	X
Remaining lower-order interactions	X	X	X	X	X
Treated jurisdictions	68	68	69	69	69
Countries	73	73	74	74	74
Observations	380	380	379	379	377
R^2	0.280	0.259	0.303	0.297	0.344

This table reports purchasing-capacity and fiscal comparisons. The dependent variable is Δ government share of healthcare expenditure, in percentage points, over $g+1$–$g+3$ relative to $g-1$. Pre-event moderators are standardized. The exposure coefficient is evaluated at their mean, and triple interactions measure its variation. Panel A compares GDP and capped-GDP weights. Panel B uses GDP weights. Parentheses contain country-cluster CR2 standard errors. ***, ** and * denote 1%, 5% and 10% significance.

TABLE 5
Public purchasing capacity and the financing response (continued)

Panel C: Private financing structure

Variables	(1)	(2)	(3)
Specification	Out-of-pocket share	Voluntary insurance	Both shares
Reliance × prior import exposure	3.137**	3.162***	3.748***
	(0.830)	(0.853)	(0.994)
Reliance × exposure × Household-financing share	0.239	—	-0.458
	(0.980)		(0.830)
Reliance × exposure × Voluntary-insurance share	—	-1.464	-1.251
		(1.718)	(1.006)
Documented reliance arrangement	2.082**	1.991**	2.032**
	(0.599)	(0.699)	(0.676)
Prior import exposure	-1.505	-2.281***	-2.406***
	(0.979)	(0.584)	(0.461)
Household-financing share	-1.570	—	-3.076**
	(1.146)		(1.024)
Voluntary-insurance share	—	1.144	-0.012
		(0.683)	(0.586)
Pre-reform log real GDP per person	0.739*	0.540	0.657
	(0.328)	(0.441)	(0.441)
Pre-reform government-financing share	-0.096	-0.053	-0.172**
	(0.068)	(0.040)	(0.058)
Earlier government-financing trend	0.127	0.029	0.115
	(0.263)	(0.240)	(0.220)
Country FE (differenced)	X	X	X
Date-group FE	X	X	X
Remaining lower-order interactions	X	X	X
Treated jurisdictions	69	65	65
Countries	74	70	70
Observations	381	362	362
R^2	0.288	0.344	0.415

This table reports private-payer comparisons. The dependent variable is Δ government share of healthcare expenditure, in percentage points. GDP-weighted regressions use standardized pre-event household and voluntary-insurance shares. Voluntary insurance is WHO scheme HF.2.1. The exposure coefficient is evaluated at the mean payer mix. Parentheses contain country-cluster CR2 standard errors. ***, ** and * denote 1%, 5% and 10% significance.

controls and weights across outcomes in equation (4.3). The exposure coefficient is 5.27 percentage points for the public-financing share, -2.25 points for the household share and -1.90 points for medical borrowing (Table 6, Panel C). The positive public-financing gradient also appears on this common survey-linked sample.

5.5 Alternative explanations and regulatory scope

The financing and survey tests show how outcomes differ with prior import dependence. We next examine economic conditions that could influence both the adoption of reliance and the ability to finance care. Using the supplementary 17-jurisdiction national-route sample, we add prior income, outcome paths, demography, debt and macroeconomic measures to equation (4.3). The exposure coefficient is 3.57 percentage points in the baseline and 3.64 points with changes in income, prices and exchange rates (Table 7, Panel A). The financing association remains positive after accounting for these economic conditions.

Two related explanations concern general trade integration and pandemic pressures. Import-dependent countries may differ in their broader trading relationships or in the financing demands created by COVID. We therefore add trade and pandemic measures to the financing regression. The exposure coefficient is 3.51 percentage points with reported mortality, 2.97 points with containment stringency and 2.95 points with both (Table 7, Panel B). Adding machinery-import or total-import exposure gives 3.30 and 2.99 points. The positive financing gradient persists in these trade and pandemic comparisons.

Regulatory coverage and comparison weights.

In untabulated tests, we vary country, population and square-root-population weights, balance repeated country roles, extend follow-up and jointly estimate government share, household share and total spending. These checks assess whether country size, repeated comparison roles, the response window or correlated financing outcomes account for the pattern. On the earlier 62-jurisdiction support, population weighting gives coefficients of 1.83 and 1.46 percentage points, while joint estimation gives 0.50 and 0.68 points. Extending the separate 48-jurisdiction comparison to six full post-event years gives 0.79 and 1.61 points. These estimates retain the positive direction of the headline result, with magnitudes that vary across weights and horizons. The checks complement the event-timing design by assessing dependence on weighting, follow-up and equation specification. The Online Appendix reports the full comparisons.

The treatment calendar records when a programme is available. We also ask whether a named reliance procedure appears in observed product registrations. WHO records identify 964 national registrations across 34 countries, covering 274 product identifiers and

TABLE 6

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)
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)
Common sample and fixed effects for Panels A–B						
Country FE (differenced)	X	X	X	X	X	X
Region FE	—	—	—	—	—	—
Date-group FE	X	X	X	X	X	X
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

Variables	(1)	(2)	(3)	(4)	(5)
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	X	X	X	X	X
Survey-pair FE	X	X	X	X	X
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 reports spending decompositions and survey-linked comparisons. The dependent variables are Δ log spending and financing fractions in Panels A–B, except column (6), which measures Δ government share in percentage points. Spending is current US dollars per person. Panel B adds prior income and growth. Panel C links financing shares, medical borrowing and purchasing-power-adjusted spending to Findex dates. Parentheses contain country-cluster standard errors, CR1 in A–B and CR2 in C. ***, ** and * denote 1%, 5% and 10% significance.

TABLE 7
Economic conditions and common-shock robustness

Panel A: Economic conditions

Variables Specification	(1) Baseline	(2) Demography	(3) Public debt	(4) 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 (differenced)	X	X	X	X
Region FE	—	—	—	—
Date-group FE	X	X	X	X
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 reports supplementary national-route financing regressions with economic controls. The dependent variable is Δ government share of healthcare expenditure, in percentage points, over the first three full post-event years relative to $g-1$. The exposure interaction uses the fixed standardized pre-event log medicine-import-to-GDP ratio. Columns (1)–(4) report the baseline, demographic, public-debt and macroeconomic specifications on 146 observations across 33 countries, including 17 treated jurisdictions. Country differencing, date-group effects, prior income, outcome level and trend enter every column. Columns (2)–(4) add prior real GDP growth; the remaining controls are displayed. Treated-country weights are equal and comparison mass is normalized by date group. Sources are national legal records, UN Comtrade, World Bank/WHO health accounts and macroeconomic series. Parentheses contain CR1 standard errors clustered by country. ***, ** and * denote significance at 1%, 5% and 10%.

TABLE 7
Economic conditions and common-shock robustness (continued)

Panel B: Pandemic and 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 (differenced)	X	X	X	X	X
Region FE	—	—	—	—	—
Date-group FE	X	X	X	X	X
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 reports national-route financing regressions with pandemic and macroeconomic controls. The dependent variable is Δ government share of healthcare expenditure, in percentage points, over three full post-event years relative to $g-1$. Prior exposure is the standardized pre-event log medicine-import-to-GDP ratio. Columns (1)–(5) report the baseline, reported mortality, containment stringency, joint pandemic and macroeconomic specifications. Mortality is reported deaths per million; stringency is a 0–100 index, each mapped to the outcome window. Columns use 137–146 observations across 33 countries and 16–17 treated jurisdictions. Country differencing, date-group effects, prior income, outcome level and trend are included. Comparison weight mass is normalized to equal-treated-country mass by date group. Sources include UN Comtrade, World Bank/WHO health accounts, Our World in Data and OxCGRT. Parentheses contain CR1 standard errors clustered by country. ***, ** and * denote significance at 1%, 5% and 10%.

941 distinct product–country pairs.[1] The register links products and authorization holders to destinations and registration dates. These observations provide product-level evidence of use of the WHO collaborative-registration pathway.

National legal profiles and initial resources.

The event comparisons examine changes around documented arrangements. A parallel question is how public-financing levels differ with national legal requirements and economic resources. Following Djankov et al. (2002), we estimate

$$G_c = a + L_c'\eta + W_c'\gamma + \varepsilon_c, \tag{5.3}$$

where G_c is the government share of healthcare expenditure in 2023, L_c contains the legal indicators, and W_c includes 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 (Online Appendix). Income is the clearest cross-country correlate. This places differences in legal requirements alongside the domestic purchasing resources available to finance care.

5.6 Government spending and the financing shift

The text analysis and common-medicine comparison identify the procedural opportunity. Qualifying foreign approvals and usable reports can make alternative authorization routes available to a supplier. The financing regressions address the subsequent allocation of healthcare payments. We now bring these two parts of the argument together by asking whether the larger government share reflects expanding public expenditure or contracting payments from other sources. Following the profit-incentive logic of Acemoglu and Linn (2004), the model connects suppliers' authorization opportunities to the treatments public payers choose to fund. We estimate government, household and total expenditure using the same treatment, exposure measure, observations and weights as the expanded financing regression to locate the spending components behind the headline result.

In the GDP-weighted 69-jurisdiction comparison, a roughly 2.25-fold difference in prior medicine imports relative to GDP is associated with 7.8% higher government healthcare expenditure per person, 2.8% higher total expenditure and 2.7% lower household expenditure after reliance arrangements, relative to comparison countries (Table 8, Panel

[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.

A). We estimate equation (4.3) separately for the log of each spending component. Government expenditure grows faster than total expenditure. This pattern locates the larger government share in a greater public contribution to healthcare spending.

The spending estimates indicate a larger public contribution. We complete the decomposition by asking which financing shares move alongside it. On the same observations and weights, the government share rises by 2.42 percentage points, while the household share falls by 1.09 points and other financing sources by 1.33 points (Table 8, Panel B). The model allows public coverage to finance additional treatment and to take over existing household bills. The common-sample decomposition locates the headline financing pattern in government's larger role in paying for healthcare. The model supplies the proposed entry-and-coverage channel, while these estimates identify its aggregate financing counterpart.

6 Conclusion

We link a legal corpus drawn from a search of 250 countries and areas, with national passages from 134 jurisdictions, 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 matched published route menus, an additional qualifying foreign approval offers a shorter review target, conditional on the required reports and other eligibility criteria.

In the GDP-weighted comparison of 69 treated jurisdictions, a one-standard-deviation increase in prior medicine-import dependence is associated with a 2.42-percentage-point larger increase in the government financing share. The separate national-route treatment definition gives 4.28 points across 30 treated jurisdictions. 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.

TABLE 8
Domestic public financing and expenditure composition

	Panel A Spending (logs)			*Panel B Financing shares*			*Panel C National routes*		
Variables	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Outcome	Govt.	Total	House-holds	Govt.	House-holds	Other	Medicine imports	Household spending	Govt. spending
Reliance × prior import exposure	0.075	0.028	-0.028	2.422*	-1.092	-1.330	—	—	—
	(0.061)	(0.060)	(0.058)	(0.936)	(0.796)	(1.276)			
Documented reliance arrangement	-0.054	-0.090*	-0.100**	Included			0.078	-0.109**	0.057
	(0.042)	(0.035)	(0.034)				(0.084)	(0.042)	(0.058)
Prior import exposure	-0.001	0.029	0.087**	Included			—	—	—
	(0.059)	(0.041)	(0.031)						
Pre-reform log real GDP per person	-0.018	-0.029	-0.038	Included			—	—	—
	(0.027)	(0.021)	(0.023)						
Pre-reform government-financing share	0.001	0.002	0.001	Included			—	—	—
	(0.002)	(0.002)	(0.002)						
Earlier government-financing trend	0.024	0.023	0.024	Included			—	—	—
	(0.025)	(0.024)	(0.020)						
Implied percentage change	7.8%	2.8%	-2.7%	—	—	—	8.1%	-10.3%	5.8%
Country FE (differenced)	X	X	X	X	X	X	X	X	X
Date-group FE	X	X	X	X	X	X	X	X	X
Treated jurisdictions	69	69	69	69	69	69	20	20	20
Countries	74	74	74	74	74	74	35	37	37
Observations	381	381	381	381	381	381	194	247	247
R^2	0.313	0.409	0.437	0.246	0.188	0.246	0.165	0.460	0.191

This table reports spending and financing composition. The dependent variables are Δ log spending per person in Panels A and C and Δ financing shares in percentage points in Panel B, measured over $g+1$–$g+3$ relative to $g-1$. Panels A–B use the 69-jurisdiction GDP-weighted sample with identical observations, exposure and controls. The exposure interaction uses the standardized prior log medicine-import-to-GDP ratio. Implied changes are $100[\exp(\widehat{\beta})-1]$. Other sources include external and remaining private financing. Panel C instead reports arrangement coefficients in the supplementary national-route samples, with equal treated-country weights. Comparison weight mass equals treated mass within each date group. All panels remove country effects by differencing and include date-group effects. Panels A–B also control for prior income, government-financing level and trend. Sources are institutional histories, UN Comtrade and World Bank/WHO health accounts. Parentheses contain country-cluster standard errors, CR2 with Satterthwaite tests in Panels A–B and CR1 with country-cluster degrees of freedom in Panel C. ***, ** and * denote 1%, 5% and 10% significance.

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A Proofs for the entry and public-coverage model

This appendix proves Propositions 3.1 and 3.2 in Section 3. It uses that section's notation, fixed prices and internationally available medicines. The comparisons hold other health-care expenditure fixed.

A.1 Entry and credible assessments

Proof of Proposition 3.1. A supplier enters when its application cost is below

$$c_r^* = e^{-\rho d_r}\Pi_j(q_r) - f_r.$$

Operating value is nonnegative and nondecreasing in perceived quality. Since $d_1 \leq d_0$, $f_1 \leq f_0$ and $q_1 \geq q_0$, the change in the cutoff can be written as

$$\begin{aligned} c_1^* - c_0^* = e^{-\rho d_1}\big[\Pi_j(q_1) - \Pi_j(q_0)\big] \\ + \big[e^{-\rho d_1} - e^{-\rho d_0}\big]\Pi_j(q_0) + (f_0 - f_1) \geq 0. \end{aligned}$$

Each term is nonnegative. Monotonicity of the cost distribution therefore gives

$$N_1 - N_0 = M_j\big[F_j(c_1^*) - F_j(c_0^*)\big] \geq 0.$$

The inequality is strict precisely when the interval between the two cutoffs contains positive probability mass and $M_j > 0$. Continuity makes the treatment of indifferent suppliers irrelevant. Extending F_j by zero below its nonnegative support also covers an initially unprofitable market.

Holding the cutoff response and cost distribution fixed, define $\delta_j = F_j(c_1^*) - F_j(c_0^*)$. The absolute response is $M_j\delta_j$, with derivative δ_j with respect to the potential medicine pool. It is strictly larger for a larger pool when $\delta_j > 0$. □

The confidence condition follows directly from the information structure. A favorable assessment with likelihood ratio $\ell > 1$ gives

$$q_1 - q_0 = \frac{q_0(1-q_0)(\ell-1)}{1 - q_0 + \ell q_0} > 0, \qquad 0 < q_0 < 1.$$

If the assessment is already incorporated in beliefs, $q_1 = q_0$. The entry comparison still holds through lower filing costs or delay. It does not require a second increase in confidence from evidence already known to purchasers.

A.2 The public-coverage choice

Write $v_r = a_j q_r + b_j n_r - \lambda_j$ and $u_r = \min\{1, K_j/A_r\}$. Because $A_r > 0$, the coverage problem is equivalent to

$$\max_{0 \le s \le u_r} \left\{ v_r s - \frac{\kappa_j}{2} s^2 \right\}.$$

The feasible interval is nonempty and compact. Its objective has second derivative $-\kappa_j < 0$, so the maximizer is unique.

Proof of Proposition 3.2, coverage. The unconstrained optimum is v_r/κ_j. Projecting it onto $[0, u_r]$ yields

$$s_r^* = \min\left\{1, \frac{K_j}{A_r}, \max\left[0, \frac{a_j q_r + b_j n_r - \lambda_j}{\kappa_j}\right]\right\},$$

which is equation (3.3). Equivalently, with multipliers $\mu_r, \nu_r \ge 0$ on $s \ge 0$ and $s \le u_r$, the conditions are

$$v_r - \kappa_j s_r + \mu_r - \nu_r = 0, \quad \mu_r s_r = 0, \quad \nu_r(u_r - s_r) = 0.$$

They are necessary and sufficient by strict concavity. If $v_r \le 0$, coverage is zero. If $0 < v_r < \kappa_j u_r$, coverage is v_r/κ_j. If $v_r \ge \kappa_j u_r$, coverage reaches its upper bound.

Favorable informative evidence raises q_r. When visibility does not fall, $a_j, b_j \ge 0$ imply $v_1 \ge v_0$. If the budget is nonbinding in both regimes, coverage equals $\min\{1, \max\{0, v_r/\kappa_j\}\}$, a nondecreasing function of v_r. Hence $s_1^* \ge s_0^*$. □

For an interior choice without a binding budget,

$$\frac{\partial s^*}{\partial q} = \frac{a_j}{\kappa_j}, \qquad \frac{\partial s^*}{\partial n} = \frac{b_j}{\kappa_j}, \qquad \frac{\partial s^*}{\partial \lambda_j} = -\frac{1}{\kappa_j}.$$

When the budget binds below full coverage, $s^* = K_j/A_r$. Additional budget raises coverage at rate $1/A_r$, whereas a larger eligible bill reduces the financed fraction at rate $-K_j/A_r^2$. These are conditional implications of the same coverage problem. A larger treatment pool need not raise the public share when the available budget is fixed and binding.

A.3 Expenditure and financing incidence

Let E_j be fixed expenditure on other healthcare, B_j its government-financed component and H_j its household-financed component. Remaining financing sources may cover $E_j - B_j - H_j$. For the eligible treatment bill,

$$G_r = B_j + s_r^* A_r, \qquad T_r = E_j + A_r, \qquad H_r = H_j + (1 - s_r^*)A_r.$$

Thus $S_r = G_r/T_r$ is the government share of all healthcare spending, the outcome corresponding to the expenditure comparison.

Proof of Proposition 3.2, financing. Using $\Delta s = s_1^* - s_0^*$ and $\Delta A = A_1 - A_0$, government and total spending change by

$$\Delta G = A_0 \Delta s + s_1^* \Delta A, \qquad \Delta T = \Delta A.$$

The exact change in the government share is therefore

$$\begin{aligned} S_1 - S_0 &= \frac{\Delta G - S_0 \Delta T}{T_1} \\ &= \frac{A_0 \Delta s + (s_1^* - S_0)\Delta A}{T_1}. \end{aligned}$$

Since $T_1 > 0$, its sign is the sign of the numerator, proving equation (3.4). Household spending changes by

$$H_1 - H_0 = (1 - s_1^*)\Delta A - A_0 \Delta s.$$

It falls precisely when $A_0 \Delta s > (1 - s_1^*)\Delta A$, as stated in the proposition. □

The first term in the share numerator is the public assumption of part of an existing treatment bill. The second compares the government contribution to additional treatment with its initial share of all healthcare. If the eligible bill is unchanged, greater coverage shifts payment from households to government without changing total expenditure. If coverage is unchanged but treatment expands, the government share rises when the new treatment's public contribution exceeds the initial financing share.

These identities also permit public spending to grow while household spending falls. This requires the coverage transfer to exceed the household-financed portion of additional treatment. The comparison is about the allocation of an existing or expanded treatment bill. It does not require regulatory operating savings to equal the change in healthcare expenditure.

B Key regression variables

TABLE B.1
Key variables and their construction

Variable	Definition and construction
Government-financing share	Domestic government health expenditure divided by current total health expenditure, multiplied by 100. Source is World Bank/WHO health accounts.
Δ government-financing share	Mean share in $g+1$, $g+2$ and $g+3$, minus the share in $g-1$. The event year is excluded. Units are percentage points.
Documented reliance arrangement	One for the treated country in an event group and zero for eligible later-treated comparisons. Expanded events use the earliest national, WHO or EU/EEA event. National-route events use domestic routes alone.
Prior import exposure	Mean log HS3004 medicine imports relative to nominal GDP over $g-4$–$g-2$. Standardization uses a fixed mean of -5.271965 and standard deviation of 0.809194. One unit represents a 2.25-fold import-dependence difference. Sources are UN Comtrade and World Bank.
Reliance $\times$ prior import exposure	The arrangement indicator multiplied by standardized prior exposure. Its coefficient measures the treated–comparison difference in the financing response per exposure standard deviation.
Pre-reform log real GDP per person	Natural logarithm of real GDP per person in $g-1$, using World Bank constant-dollar income.
Pre-reform government-financing share	Government-financing share in $g-1$, measured in percentage points.
Earlier government-financing trend	Government share in $g-1$ minus its value in $g-4$, divided by three. Units are percentage points per year.
Spending components	Domestic government, household out-of-pocket and total current healthcare expenditure per person. Spending regressions use the post-minus-pre change in natural logarithms. Source is World Bank/WHO.
Medical borrowing and financial hardship	Findex borrowing for medical expenses and WHO financial hardship or impoverishing spending. Survey regressions use percentage-point changes between waves.

This table shows the construction of the principal regression variables. g denotes the qualifying event year. Annual changes compare the first three full subsequent years with the preceding year. Survey outcomes use their observed survey dates.

C Illustrative regulatory provisions

The extracts below illustrate distinct conditions coded in the legal corpus. Quotations reproduce the English wording of the preserved official sources, with line breaks normalized. The accompanying explanations describe the relevant legal component.

United Kingdom. Access to full assessment reports

"Full unredacted assessment reports from the referencing authority will be required to support the IRP application. It is the responsibility of the applicant to provide the requested documentation."
The applicant must supply scientific reports as well as a foreign authorization. Source is MHRA, International Recognition Procedure, guidance on reference-regulator approvals.

Singapore. Number and independence of foreign approvals

"Has been approved by at least two of our reference drug regulatory agencies at the time of submission. The product has received full marketing approval by the reference agencies following a complete independent scientific assessment."
This verification route conditions eligibility on multiple prior approvals and independent assessments. Source is HSA, Evaluation routes, new-drug verification criteria.

Australia. Matching the domestic and foreign products

"the strength, dosage form, formulation and directions for use of the evaluation medicine are identical to those of the acceptable foreign approved medicine"
The foreign credential must concern a product matching the domestic application. Source is Therapeutic Goods Regulations 1990, regulation 16DA(1)(d), compilation of 1 July 2024.

South Africa. Continuing domestic evidence requirements

"SAHPRA reserves the right to request any additional information to establish the safety, efficacy, and quality of a medicine in keeping with the knowledge current at the time of evaluation."

Reliance retains a domestic power to seek further evidence. Source is SAHPRA, Reliance Guideline, version 5, 6 August 2025, general requirements.