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The Enactment Gap: A Comparative Diagnosis of Institutional Health in Pharmaceutical Governance

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شکاف اجرا: تشخیص تطبیقی سلامت نهادی در حکمرانی دارویی

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چکیده

ادبیات تطبیقی حکمرانی دارویی عمدتاً بر دو پرسش متمرکز است: یک کشور تا چه اندازه تنظیم‌گری می‌کند و نظام آن چه عملکردی دارد. هر دو پرسش، مسئله‌ای مقدم‌تر را بی‌پاسخ می‌گذارند: آیا نهادهایی که این تنظیم‌گری را انجام می‌دهند، خود در وضعیت سالمی قرار دارند؟ این مقاله مفهوم «شکاف اجرا» را به‌عنوان فاصله قابل سنجش میان آنچه یک قاعده حکمرانی وعده می‌دهد و آنچه ذی‌نفعان در عمل تجربه می‌کنند، به‌مثابه ابزاری تشخیصی برای سنجش سلامت نهادی در سطح نظام صورت‌بندی می‌کند. پنج کشور با معماری تنظیم‌گری متفاوت — دانمارک، آلمان، مالزی، برزیل و ترکیه — مقایسه شده‌اند و ایران بر پایه مطالعه پیشین نویسنده در سطح بنگاه، به‌عنوان مورد مرجع در نظر گرفته شده است. طرح پژوهش، مقایسه ساختاریافته و متمرکز بر پایه پیکره‌ای هدفمند از سی‌ویک سند تنظیم‌گرانه، سازمانی و ارزیابانه منتشرشده در بازه ۲۰۱۰ تا ۲۰۲۶ است. هر کشور دو بار و بر پنج بُعد نیمرخ سلامت نهادی ارزیابی شده است: یک بار در برابر قواعد رسمی و یک بار در برابر پیامدهای مستند، و واگرایی میان این دو قرائت در مقیاسی رتبه‌ای و سه‌سطحی کدگذاری شده است. یافته اصلی آن است که پهنای شکاف اجرا نه از تراکم تنظیم‌گری پیروی می‌کند و نه از سطح درآمد ملی. دانمارک و آلمان در دو سر طیف تراکم قاعده قرار دارند اما هر دو شکاف باریکی را حفظ می‌کنند، در حالی که ترکیه و برزیل با تراکم قابل مقایسه، واگرایی شدیدی نشان می‌دهند. آنچه این دو گروه را از هم جدا می‌کند، وجود «مجرای تصحیح» است: مسیری متعارف، کم‌هزینه و نهادی که شکاف را آشکار و برای قاعده‌گذار پرهزینه می‌سازد. هرجا چنین مجرایی وجود دارد، شکاف بدون نیاز به اصلاح ساختاری بسته می‌شود و هرجا غایب است، کیفیت صوری قواعد مانع تهی‌شدن آن‌ها نمی‌گردد. در پایان، گونه‌شناسی چهارگانه‌ای استخراج شده و دلالت آن برای ایران چنین است که سرمایه‌گذاری بر زیرساخت آشکارسازی شکاف، احتمالاً بازدهی بیشتری از قاعده‌گذاری افزون‌تر خواهد داشت.

Abstract

Comparative work on pharmaceutical governance is dominated by two questions: how much a country regulates, and how well its system performs. Both leave a prior question unasked — whether the institutions doing the regulating are themselves in sound condition. This article develops the enactment gap, the measurable distance between what a governance rule promises and what stakeholders actually experience, as a diagnostic of institutional health at system level. Five countries with sharply different regulatory architectures are compared: Denmark, Germany, Malaysia, Brazil and Türkiye, with Iran as a reference case drawn from the author's earlier firm-level study. The design is a structured focused comparison built on a purposive corpus of thirty-one regulatory, agency and evaluative documents published between 2010 and 2026. Each country is assessed twice on the five dimensions of the Institutional Health Profile — functional integrity, burden parsimony, responsiveness to suffering, trustworthiness and regenerative capacity — once against its formal rules and once against documented outcomes, with the divergence between the two readings coded on an ordinal three-band scale. The central finding is that the width of the enactment gap tracks neither regulatory density nor national income. Denmark and Germany occupy opposite extremes of rule density yet both keep narrow gaps, while Türkiye and Brazil are comparably dense and diverge sharply. What separates them is the presence of a corrective channel: a routine, low-cost, institutionally protected route through which the gap is surfaced and made costly to the rule-maker. Where such a channel exists, gaps close without reform; where it is absent, formal rule quality does not prevent hollowing. A four-cell typology is derived, and the implication for Iran is that investment in gap-surfacing infrastructure is likely to yield more than further rule-making.

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Keywords: Institutional health, enactment gap, pharmaceutical governance, comparative institutional analysis, regulatory decoupling.

کلمات کلیدی: سلامت نهادی، شکاف اجرا، حکمرانی دارویی، تحلیل نهادی تطبیقی، واگرایی تنظیم‌گرانه.

1. Introduction

Every national pharmaceutical system rests on a set of promises written into law. Prices will be set by a stated method. Marketing authorisation will follow a published procedure. Reimbursement decisions will be reasoned and appealable. Shortages will trigger a defined response. These promises are the visible surface of pharmaceutical governance, and they are what comparative research most often measures.

What such measurement cannot see is whether the promises hold. A pricing decree that fixes a conversion rate far below the market rate remains, on paper, a functioning pricing mechanism. A right of appeal that is never exercised remains, on paper, a right. An agency mandated to publish performance data remains, on paper, transparent. In each case the rule is intact and the institution is hollow.

This article takes that divergence as its object. It proposes the enactment gap — the distance between what a governance rule promises and what stakeholders actually experience — as a diagnostic of institutional health at system level, and asks what makes the gap narrow in some systems and wide in others.

The question matters for two reasons. The first is diagnostic. Reform programmes in middle-income pharmaceutical systems routinely respond to poor outcomes by writing new rules, on the implicit assumption that the existing rules failed because they were badly designed. If the binding constraint is enactment rather than design, that response adds regulatory burden without improving outcomes. The second reason is theoretical. Sociological institutionalism has long described the decoupling of formal structure from actual practice (Meyer & Rowan, 1977), but it treats decoupling largely as a legitimacy strategy. It says little about why some systems close the gap and others live with it indefinitely.

The empirical strategy is comparative. Five countries with sharply different regulatory architectures are examined — Denmark, Germany, Malaysia, Brazil and Türkiye — with Iran included as a reference case drawn from the author's earlier firm-level study of institutional health in the Iranian pharmaceutical sector (Mahdavian Sadr, 2026). Each system is read twice: once against its formal rules and once against documented outcomes. The divergence between the two readings is the finding.

The article proceeds as follows. Section 2 develops the theoretical basis, linking institutional health theory to the decoupling literature and situating the enactment gap between them. Section 3 sets out the comparative design, the document corpus and the assessment rubric. Section 4 reports the country assessments and the cross-case pattern. Section 5 discusses the central finding — that corrective channels, not rule quality, govern gap width — and Section 6 draws implications.

2. Theoretical Background

2.1 Institutional health

The concept of organisational health originates with Miles (1969), who defined a healthy organisation as one that not only survives in its environment but retains the capacity to adapt and grow. Hoy and Feldman (1987) turned the idea into an instrument, but its application remained largely confined to schools and its components addressed climate and human relations rather than the structure of rules.

Institutional health enters from a different direction. If institutions are, in North's (1990) sense, the formal and informal rules governing interaction, then asking about their health is asking about the quality of those rules. The formulation used here defines institutional health as the capacity of an institution to realise its constitutive purpose over time, under ordinary conditions, without generating

avoidable suffering, and specifies five dimensions: functional integrity, burden parsimony, responsiveness to suffering, trustworthiness and regenerative capacity (Mahdavian Sadr, 2026).

Two distinctions carry weight. Health is not efficiency: a system that meets its targets by exhausting its workforce and its patients is not healthy under this definition. Nor is it legitimacy: an institution can preserve the appearance of propriety through ceremonial conformity while its rules fail in operation.

2.2 From decoupling to the enactment gap

That last observation is the point at which institutional health theory meets the decoupling tradition. Meyer and Rowan (1977) described organisations that adopt formal structures for legitimacy while their technical core operates on different logic. Bromley and Powell (2012) later distinguished policy–practice decoupling, where a rule is adopted but not implemented, from means–ends decoupling, where a rule is implemented but has no bearing on the outcome it was meant to produce. Both forms appear in pharmaceutical governance.

The enactment gap developed here is narrower and more operational than decoupling. It is not a claim about organisational motives; it is a measurement instruction. For any governance function, the analyst reads the formal rule and then reads the documented experience of those the rule governs, and treats the divergence as data. The gap can be observed without knowing whether it arose from cynicism, capacity failure or external shock — and that is precisely its usefulness as a diagnostic.

Framed this way, the gap is also directional. It widens when shocks — currency movements, supply disruption, fiscal contraction — outpace the rule's ability to accommodate them, and it narrows when something forces the rule-maker to confront the divergence. What that something is forms the central question of this article.

2.3 What comparative pharmaceutical governance leaves unasked

Comparative work on pharmaceutical governance is substantial but organised around two axes. The first is regulatory architecture: pricing methods, health technology assessment arrangements, procurement models (Vogler et al., 2017; Panteli et al., 2016). The second is system performance: access, expenditure, availability of essential medicines (WHO, 2021; OECD, 2023).

Neither axis captures the condition of the regulating institution itself. A country can score well on architecture because its statutes are modern and comprehensive, and poorly on performance for reasons that have nothing to do with governance quality. Conversely, a system with a thin rulebook may perform well because the few rules it has are reliably kept. Siddiqi et al. (2009) proposed a governance assessment framework for health systems in developing countries that moves in this direction, but it evaluates principles rather than the distance between principle and practice.

The contribution of this article is to place that distance at the centre of the comparison and to ask what explains its variation.

3. Method

3.1 Design

The study is a qualitative structured focused comparison (George & Bennett, 2005). The same set of questions is asked of each case, derived from the five dimensions of the Institutional Health Profile, and each is answered twice — once from the formal rule and once from documented outcome. The comparison is structured in that the question set is fixed, and focused in that only the enactment gap is examined, not the wider performance of each system.

The evidentiary base is documentary. Document analysis is treated here not as literature review but as a systematic method of qualitative data collection in which official documents serve as field data (Bowen, 2009), analysed through directed qualitative content analysis (Hsieh & Shannon, 2005).

3.2 Case selection

Cases were selected on a most-different logic, to test whether gap width covaries with the structural features that comparative work

usually treats as decisive. The selection criteria and the resulting variation are set out in Table 1.

Table 1. Case selection and structural variation

Country	Income group	Regulatory architecture	Selection rationale
Denmark	High	Thin rulebook, centralised procurement, free pricing	Low rule density with strong institutional capacity
Germany	High	Dense statutory framework, corporatist self-governance	High rule density with strong institutional capacity
Malaysia	Upper-middle	Consolidated agency, emerging price regulation	Reform in progress, contested implementation
Brazil	Upper-middle	Multi-body architecture with constitutional health right	High density, high litigation, federal complexity
Türkiye	Upper-middle	Consolidated agency, administered pricing under currency stress	Structural conditions closest to the reference case
Iran	Reference case	Consolidated agency, administered pricing, sanctions exposure	Prior firm-level evidence available

Türkiye and Iran share the combination that makes the comparison analytically useful: administered pricing set in a foreign currency, a domestic currency under sustained pressure, and a consolidated regulator. Denmark and Germany bracket the rule-density dimension at the high-capacity end. Malaysia and Brazil supply variation in how openly the gap is contested.

3.3 Document corpus

The corpus was assembled purposively against four inclusion criteria: issue by a national regulator, ministry, statutory body or peer-reviewed evaluative source; explicit treatment of pharmaceutical governance at system rather than product level; publication between 2010 and 2026; and availability in English or in an authoritative English rendering. Documents addressing a single product, a single therapeutic area or a single procurement episode were excluded. The resulting corpus comprises thirty-one documents distributed as shown in Table 2.

Table 2. Composition of the document corpus

Document type	DK	DE	MY	BR	TR	Cross-national	Total
Statute, decree or regulation	1	2	1	2	2	–	8
Agency procedure or process guide	2	2	2	1	1	–	8
Evaluative or peer-reviewed study	2	2	1	2	2	2	11
International organisation report	–	–	–	1	–	3	4
Total	5	6	4	6	5	5	31

3.4 Assessment rubric

Each country was assessed on each of the five dimensions twice. The de jure reading asks what the formal rule provides; the de facto reading asks what documented outcomes show. The divergence was then coded on a three-band ordinal scale defined in advance: a narrow gap where documented outcomes broadly match the formal provision and departures are acknowledged and addressed through existing procedure; a moderate gap where a recurring divergence is documented and contested but not resolved; and a wide gap where the formal provision is documented as systematically unrealised, or where its literal application produces the outcome it was designed to prevent.

The bands are ordinal and comparative, not metric. They support statements of the form "the gap in this dimension is wider in country A than in country B" and do not support

arithmetic. This is a deliberate constraint: the underlying evidence is documentary and heterogeneous across jurisdictions, and a numerical score would imply a precision the corpus cannot bear.

3.5 Validity

Three measures were taken. First, no dimension was assigned a gap band on the basis of a single document; each assignment rests on at least one formal source establishing the rule and at least one independent source documenting the outcome. Second, a coding audit trail linking each assignment to its supporting documents was maintained and is available. Third, the assessment was deliberately restricted to what documents can establish. Where the corpus supports a claim about the formal rule but not about its enactment, this is stated rather than inferred.

Two limitations follow from the design and are stated here rather than deferred. English-language availability biases the corpus toward jurisdictions that publish in English or are extensively studied in it; Türkiye and Brazil are less well served on this dimension than Denmark or Germany. And documentary evidence records the gaps that someone has already troubled to record, which will tend to understate gaps in systems where such recording is itself weak — a bias that runs against the article's own argument and therefore makes the reported pattern conservative.

3.6 Disclosure on the use of artificial intelligence tools

Generative artificial intelligence tools were used for language editing, reference formatting and the preparation of the graphical figures. The research question, case selection, corpus construction, coding, interpretation and all analytical claims are the author's own. The author takes full responsibility for the content of the article, including those parts prepared with the assistance of such tools.

4. Findings

4.1 Denmark: a thin rulebook, reliably kept

Denmark regulates comparatively little and enacts almost all of it. Pharmaceutical pricing is formally free; the working instrument is procurement. Amgros, established in 1990 and owned by the regions that also own the hospitals, procures nearly all hospital medicines, and hospitals are required to use it. Since 2017 the Danish Medicines Council has assessed new hospital medicines and issued recommendations that feed directly into Amgros price negotiations.

The de facto reading matches closely. Assessment-to-availability runs to a documented and predictable interval. Because the procuring body, the assessing body and the hospital owners are the same set of regions, the loop between decision and implementation is short and there is no separate compliance apparatus to circumvent.

The one point of strain is regenerative rather than integrative: as a small market, Denmark faces documented difficulty securing supply of older, low-priced medicines, which has driven cross-border joint procurement with Norway and Iceland. This is a genuine gap between the promise of continuity of supply and its realisation — but it is a gap the system has named and acted on, which is precisely the behaviour that distinguishes a narrow gap from a wide one.

4.2 Germany: dense rules, high burden, high fidelity

Germany presents the opposite architecture with a comparable result. Under AMNOG, in force since 2011, a manufacturer must submit a benefit dossier on the day of market entry; the Federal Joint Committee determines the appropriate comparator, IQWiG or the Committee assesses the dossier, the assessment is published, stakeholders may comment in writing, an oral hearing is held, and the decision on added benefit issues on a fixed timetable before price negotiation.

This is a demanding, document-heavy procedure, and burden parsimony is correspondingly the weakest dimension in the German profile. Yet the procedure is followed. What makes it so is that its own steps constitute a corrective channel: publication, the written comment period and the oral hearing force any divergence between the assessment and the clinical evidence into the open before the decision becomes final.

The system's costs are visible in the same way. Manufacturers may withdraw a product at any point in the process, and withdrawals cluster among products assessed as offering no additional benefit while remaining in clinical guidelines. Access is thereby narrowed for some patients. This is a real institutional cost — but it is documented, attributed and debated rather than absorbed silently, which again distinguishes it from a hollow rule.

4.3 Malaysia: a gap contested in the open

Malaysia is a system in mid-reform. The National Pharmaceutical Regulatory Agency operates a consolidated regulatory function under the Ministry of Health and has progressively expanded reliance on reference agencies to speed evaluation. Price transparency in the private sector, historically weak, became the object of a government directive requiring private clinics to display retail medicine prices.

The de facto reading is instructive. In 2025 seven medical associations and a practitioner applied for judicial review of the directive, arguing that it exceeded ministerial authority. The Health Minister's response was to welcome the judicial process while continuing enforcement and advocacy pending the court's decision.

It would be easy to read an open legal challenge as institutional weakness. The opposite reading is better supported. The gap between the transparency rule and its acceptance by those it binds is real, but it is being processed through a channel designed for exactly that purpose, at a cost the parties can bear, with the regulator publicly committing to abide by the outcome. That is a corrective channel functioning as intended.

4.4 Brazil: a wide gap with a powerful corrective channel

Brazil has the most elaborate architecture in the sample. ANVISA grants marketing authorisation; the Drug Market Regulation Chamber approves maximum prices, without which authorisation is not effective; CONITEC decides incorporation into the public health system; and Farmácia Popular delivers subsidised access for a defined set of indications. Constitutionally, health is an enforceable right.

The gaps are correspondingly wide. Regulated ceiling prices and prices actually obtained in public purchasing have been documented as diverging by extraordinary margins, and private-market prices for the same molecule vary by orders of magnitude. Access promised in principle is frequently not available in practice.

What distinguishes Brazil from the other wide-gap cases is the scale of its corrective channel. The constitutional health right has produced sustained litigation through which citizens compel delivery of what the rules promise, and the Supreme Court has repeatedly been forced to define the boundary — most recently, in September 2024, by restricting state liability for products authorised but not incorporated into the public system, subject to specified conditions. Litigation on this scale is an expensive and unequal way to close a gap. But it is a functioning one, and it renders the gap continuously visible and costly to the rule-maker.

4.5 Türkiye: the gap engineered into the rule

Türkiye supplies the clearest case of a formally coherent rule whose literal application produces the outcome it was meant to prevent. Pricing is governed by external reference pricing against a defined basket of European countries, taking the lowest reference price. Layered on this is a mechanism without parallel among the comparators: the euro value used in pricing is fixed administratively rather than tracking the market rate.

The consequence is documented and structural. When the administered euro rate is set well below the prevailing market rate, and the gap persists across a pricing period, domestic prices fall progressively further below replacement cost. The documented result is shortage and supply interruption — that is, a mechanism designed to protect access producing its opposite.

Read against the five dimensions, functional integrity is formally strong: the rule is clear,

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published and consistently applied. It is precisely the consistency of application that generates the harm, which is why an assessment confined to rule quality would return a favourable verdict. Trustworthiness is where the gap is widest, since the central price parameter is revised by decree at intervals that do not track the conditions it is meant to reflect. Frequent decree amendment demonstrates responsiveness of a kind, but reactive adjustment after harm has materialised is a weaker form of regenerative capacity than a mechanism that prevents the divergence.

4.6 Cross-case pattern

Figure 1 sets out the analytical structure applied to each case.

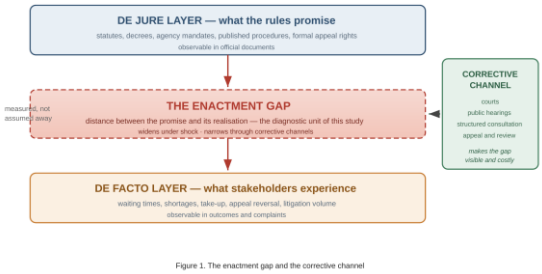

Figure 1. The enactment gap and the corrective channel

Table 3 summarises the assessment across all cases and dimensions, and Figure 2 presents the same result in profile form.

Table 3. Enactment gap by country and dimension

Dimension	Denmark	Germany	Malaysia	Brazil	Türkiye	Iran
Functional integrity	Narrow	Narrow	Moderate	Wide	Wide	Moderate
Burden parsimony	Narrow	Wide	Moderate	Wide	Wide	Wide
Responsiveness to suffering	Narrow	Moderate	Moderate	Moderate	Wide	Wide
Trustworthiness	Narrow	Narrow	Moderate	Wide	Wide	Wide
Regenerative capacity	Moderate	Moderate	Moderate	Moderate	Wide	Wide

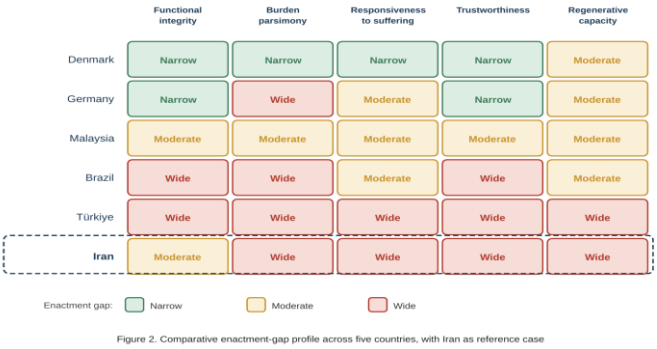

Figure 2. Comparative enactment-gap profile

Two negative results stand out. Gap width does not track regulatory density: Denmark regulates least and Germany most among the high-capacity cases, and both hold narrow gaps on most dimensions. Nor does it track income group cleanly: Brazil and Türkiye share an income classification and diverge in pattern, while Malaysia sits in the same group with narrower gaps than either.

The variable that does track gap width is set out in Table 4.

Table 4. Corrective channels compared

Country	Principal corrective channel	Cost of use	Binding on rule-maker
Denmark	Shared ownership of assessment, procurement and provision	Very low	Yes, structurally
Germany	Published assessment, comment period, oral hearing	Low to moderate	Yes, procedurally
Malaysia	Judicial review of ministerial directives	Moderate	Yes, on decision
Brazil	Constitutional health litigation	High and unequal	Yes, on judgment
Türkiye	Periodic decree amendment by the rule-maker	Not available to those affected	No
Iran	Administrative petition without published outcome	High relative to benefit	Weak

The pattern is consistent. Where a route exists through which those bound by a rule can compel the rule-maker to confront its non-realisation — and where using that route is

affordable and its outcome binding — gaps are narrow or narrowing. Where the only corrective mechanism is the rule-maker's own discretion to amend, gaps are wide and persistent.

Plotting the cases on rule density against enactment fidelity yields the typology in Figure 3.

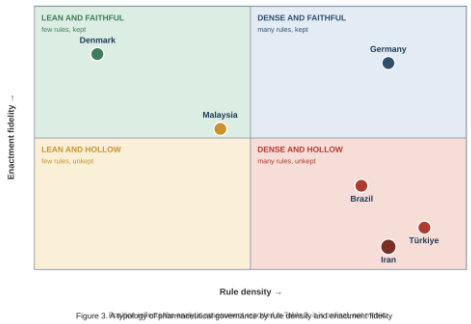

Figure 3. A typology of pharmaceutical governance

The diagonal is the informative axis. Denmark and Germany sit at opposite ends of rule density on the faithful row; Türkiye and Iran sit close together on the hollow row despite differing in the detail of their architectures. Brazil occupies an unstable position: dense and hollow by rule, but pulled toward fidelity by litigation. Malaysia sits near the centre with its direction of travel currently open.

5. Discussion

The first implication concerns the design of reform. If gap width were a function of rule quality, the appropriate response to poor pharmaceutical governance outcomes would be better rules. The comparison does not support that inference. Türkiye's pricing rule is clear, published and consistently applied, and its consistent application is the mechanism of harm. Writing a more detailed version of the same rule would not narrow the gap. Creating a route by which affected parties could compel timely revision might.

The second implication concerns what a corrective channel actually requires. Table 4 suggests three conditions rather than one. The channel must be routine, meaning available without extraordinary effort or political access; it must be affordable relative to the benefit at stake; and its outcome must bind the rule-maker. Brazil satisfies the third condition strongly and the second weakly, which is why its gaps are visible and contested but slow to close. Türkiye and Iran fail the first and third, which is why divergence can persist across pricing periods without institutional consequence.

The third implication is theoretical. Decoupling theory explains why organisations adopt rules they do not enact, but treats the persistence of decoupling as the default and its resolution as exceptional. The comparison suggests the reverse specification is more useful: decoupling persists where nothing makes it expensive, and the institutional design question is what makes it expensive. On this reading, transparency is not primarily a virtue of good governance but the precondition of a functioning corrective channel — it is what allows a gap to be demonstrated rather than merely alleged.

The fourth implication follows from the German case and cuts against a simple reading of the results. Germany carries the heaviest procedural burden in the sample and pays a documented access cost in product withdrawals. A narrow enactment gap is therefore not the same as good governance, and this article does not claim otherwise. What it claims is narrower: that the gap is a diagnostic of institutional health specifically, and that a system whose promises hold is in a different condition from one whose promises do not, whatever the separate merits of the promises themselves.

A final observation concerns the direction of causation, which the design cannot establish. It is possible that corrective channels produce narrow gaps, and equally possible that systems already disposed to keep their promises are the ones that build such channels. The documentary evidence is consistent with both. What can be said is that no case in the sample combines a functioning corrective channel with a persistently wide gap, and that the two wide-gap cases are also the two cases without such a channel.

6. Conclusion and Implications

This article has proposed the enactment gap as a diagnostic of institutional health in pharmaceutical governance and applied it across five countries with a sixth as reference.

The finding is that gap width tracks neither regulatory density nor income group, but the presence of a corrective channel through which those bound by a rule can make its non-realisation visible and costly to the rule-maker.

For Iran, whose profile in the reference study showed trustworthiness and regenerative capacity as the weakest dimensions at firm level, the comparative result carries a specific implication. The weakness identified there was not an absence of rules but a shortfall in commitment-keeping and post-shock repair — the same signature that characterises the wide-gap cases here. On the present analysis, the productive investment is not further rule-making but gap-surfacing infrastructure: publication of decision reasoning, an appeal route whose outcomes are recorded and reported, and a published interval within which a price parameter that has diverged from its own stated basis must be revisited.

Three limitations bound these conclusions. The corpus is documentary and English-biased, which understates gaps in less-documented systems. The assessment bands are ordinal analytic judgements, and although anchored in advance and audited, they are not measurements. And the design is cross-sectional, so the dynamics by which channels emerge and gaps close are inferred rather than observed.

Three extensions follow directly. The first is to operationalise gap width with quantitative proxies — appeal reversal rates, take-up shortfall against eligibility, interval between divergence and revision — and test the pattern across a larger sample. The second is to trace a single case longitudinally through the emergence of a corrective channel. The third is to apply the framework to a sector outside pharmaceuticals, where the corrective-channel hypothesis would predict the same relationship on entirely different institutional terrain.

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Conflict of Interest

The author declares no conflict of interest in relation to this research.

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Note: the primary regulatory and agency documents constituting the analytical corpus are listed in the supplementary coding file and are cited in the text by issuing body.