



A Composite Product Market Distortion Index for Regulatory Surveillance

Detecting price-volume anomalies in generic pharmaceutical markets in South Africa

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Distortions Persist Despite Price Regulation And Controls

Problem From policy design to observed market behaviour

Existing policy architecture

- **Single Exit Price** standardises list prices across the value chain
- **Mandatory generic substitution** is intended to shift utilisation toward cheaper equivalents
- **Scheme-level tools** include formularies, negotiated reimbursement, networks, and co-payments to control costs



Implication

Affordable generics can exist on the shelves while higher-cost products still dominate volume

Our Argument

- Pricing policy alone does not guarantee efficient outcomes when supplier practices, prescriber behaviour, information asymmetries, and structural features dilute price signals
- Misalignment in prices and volumes persists
- That is the gap CMDI is designed to detect

Why Current Monitoring Tools Fall Short?



Price Indicators Alone

Obscure utilisation anomalies when list prices are regulated but net prices remain opaque



Volume Indicators Alone

Reveal concentration but fail to explain whether patterns are economically rational



Combined Signal Needed

Inefficiencies arise from misalignment across indicators, not extremes in one dimension

CMDI bridges this gap - offering a holistic, actionable view of market behaviour using routinely collected data

Study Aim And Objectives

Develop and apply a **Composite Market Distortion Index** using routinely available data to detect price–volume anomalies in generic medicine markets to flag specific products and markets for regulatory review

Practical & Scalable

A screening tool for routine regulatory surveillance

Uses Existing Data

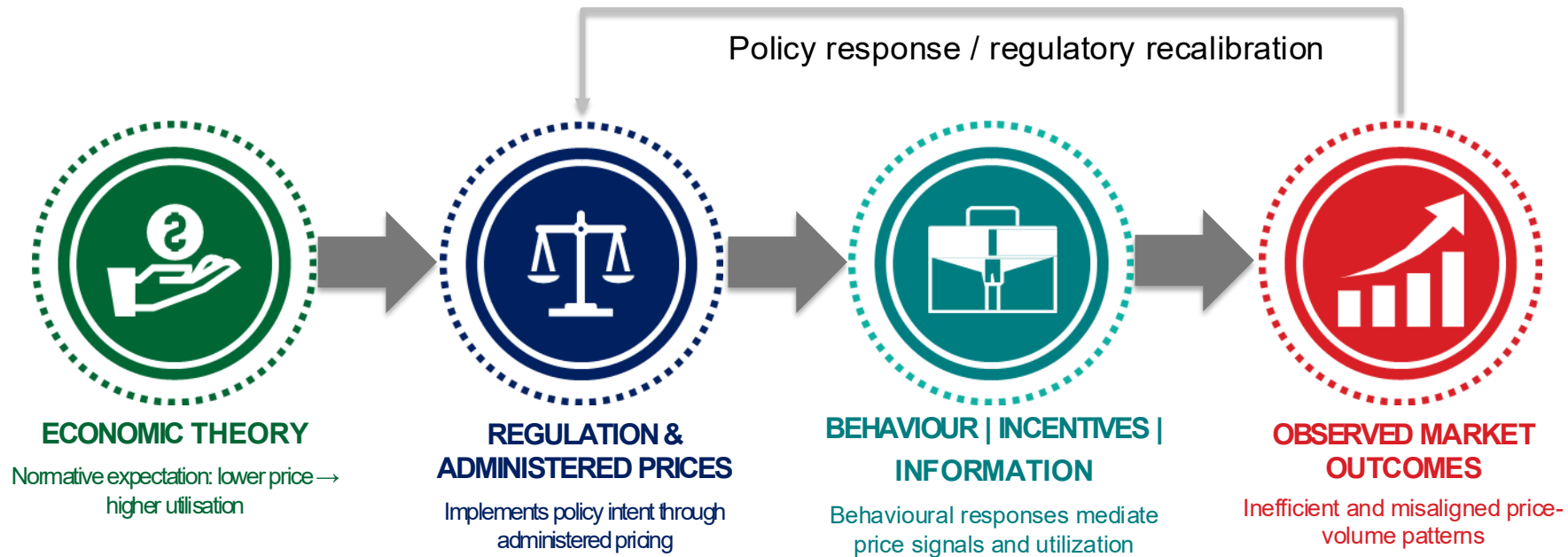
Critical for resource-constrained settings with limited budgets

Flags, Not Diagnoses

Identifies markets warranting closer scrutiny, not causality

CMDI helps prioritise regulatory attention by providing a transparent, feasible, and policy-relevant signal of price–volume misalignment.

Theoretical & Conceptual Framework



Economic theory defines the expected price-utilisation relationship; regulation shapes prices; behaviour mediates utilisation; outcomes inform regulatory response; CMDI measures price-volume misalignment.

Study Design and Scope

Design Retrospective analysis across two data environments

Market Definition & Scope

- 21 off-patent generic markets
- Product markets defined by API, dosage form, route, and strength
- Prices standardised using unit pricing principles

Dataset A | IQVIA Sales Data

- National commercial sales data
- Period: 2014–2015
- Reflects private sector pharmaceutical sales across South Africa

Dataset B | Scheme Claims Data

- Medical scheme claims data
- Period: 2020–2024
- Reflects payer-mediated utilisation with reimbursement controls

ANALYTICAL ASSUMPTION

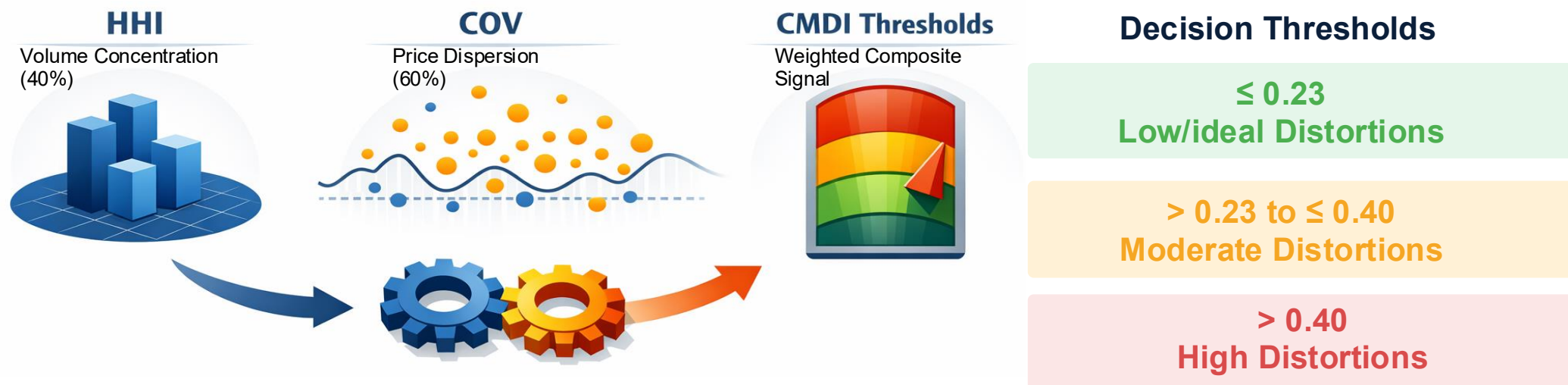
In a well-functioning market for therapeutically equivalent medicines, lower-priced products are expected to capture a larger share of volume. Distortions arise when this relationship weakens.

WHY TWO DATASETS MATTER

Using two independent datasets supports validation across time, context, and data source rather than relying on a single snapshot

How CMDI Detects Distortions

Indicators The CMDI is a compact screening tool rather than a causal test



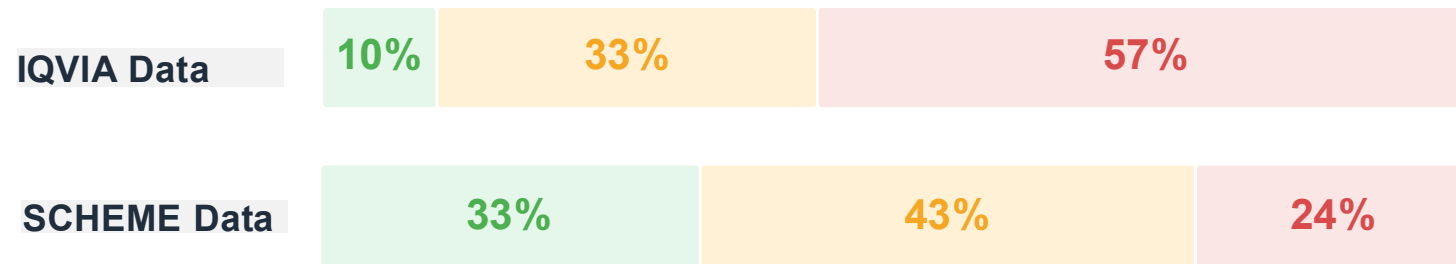
CMDI does not diagnose misconduct - it screens and prioritises products (implied supplier) and markets where price-volume relationships look inconsistent with the outcomes of a well-functioning generic products market

Headline Result: Distortion is Widespread - But Uneven

Results

CMDI distribution by dataset

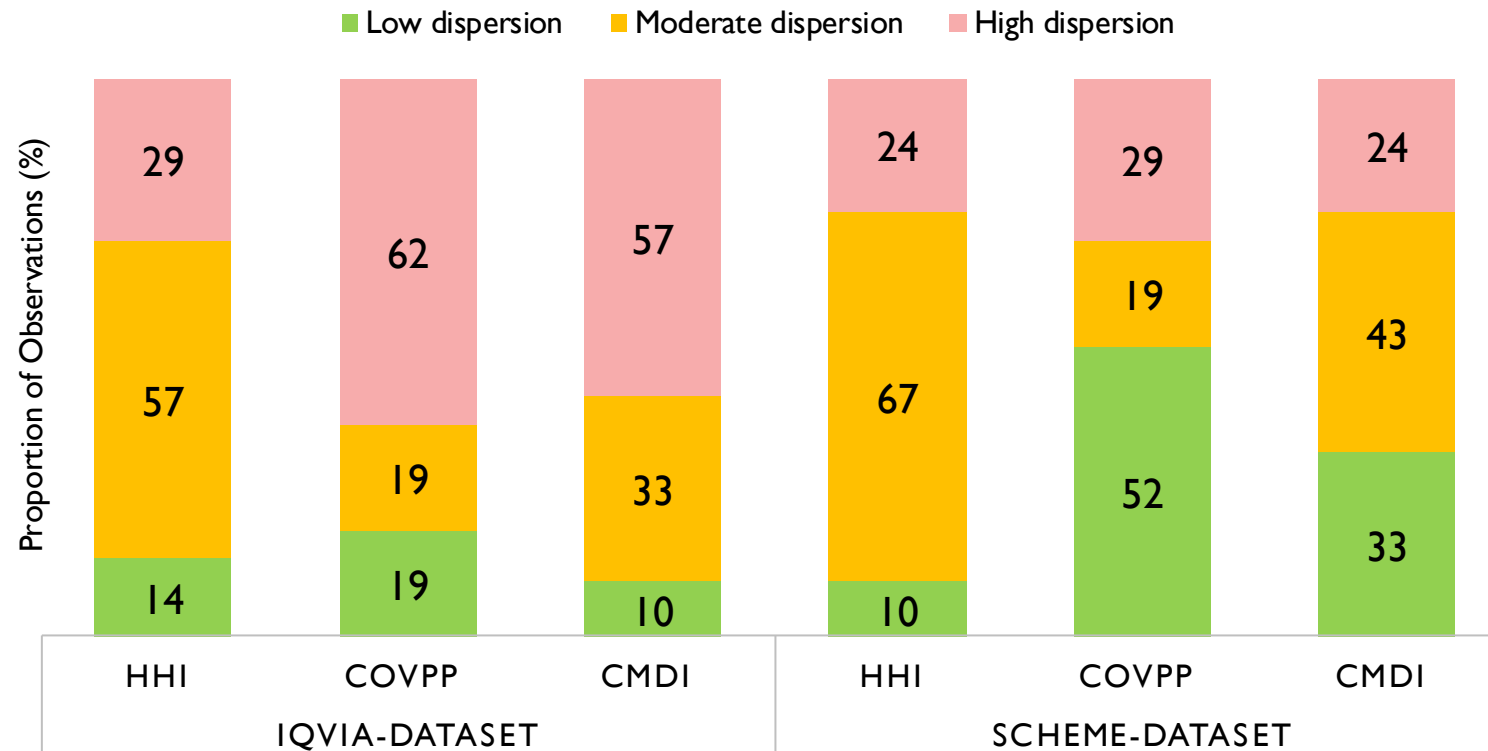
CMDI distribution across 21 product markets:



National market data shows more pronounced distortion than scheme claims data, but neither environment is distortion-free

Where the Signal Comes From: Price Dispersion and Misalignment

Analytics Indicator-level contrast between datasets

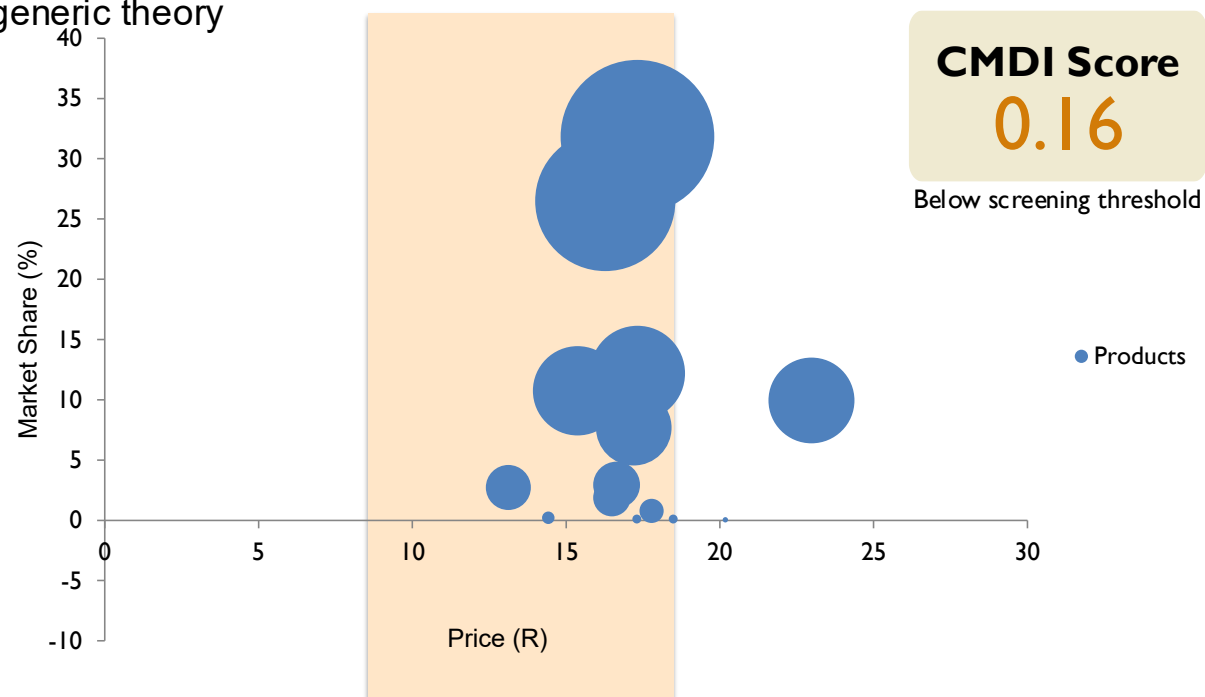


CMDI provides a clearer and more consistent signal of price-volume misalignment across datasets than existing indicators.

Example of Aligned Market: Cefuroxime Axetil

Price–Volume Relationship

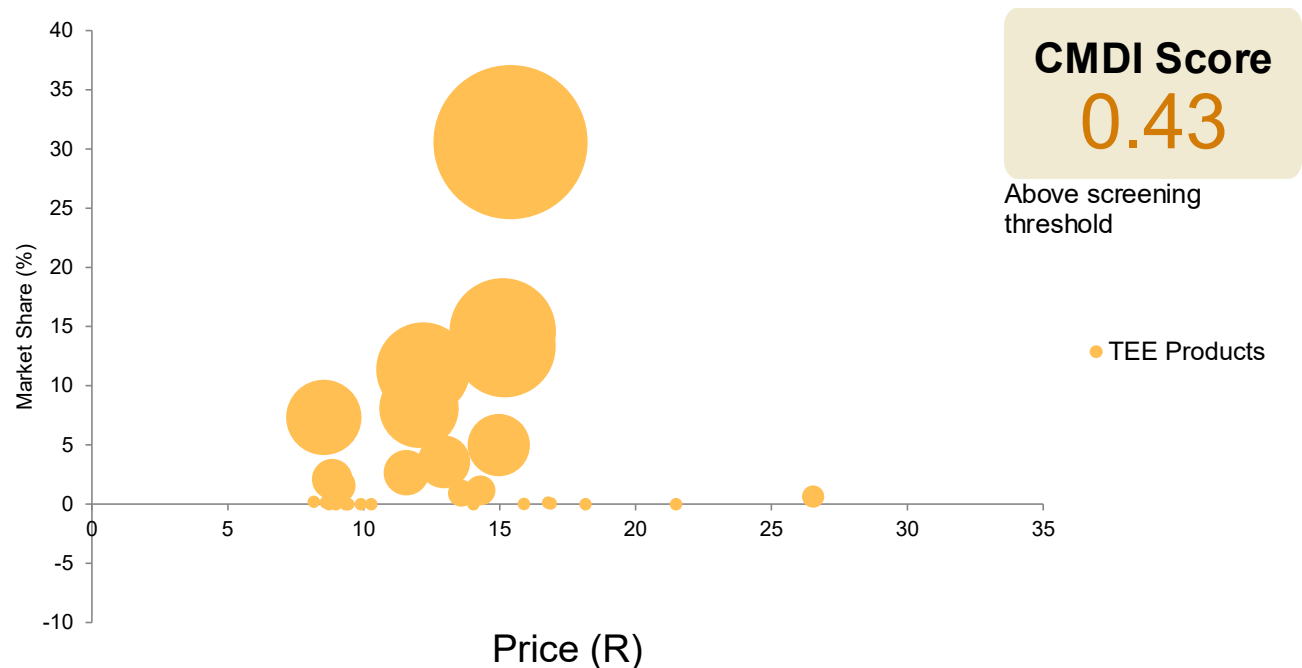
Expected relationship: Product prices cluster closely, and market shares distribute relatively evenly - consistent with competitive generic theory



Example of a Distorted Market: Tenofovir-Emtricitabine-Efavirenz (TEE)

Price–Volume Relationship

Unexpected relationship: A 5× price difference between products, yet the highest-priced option captures ~40% of total volume - a clear misalignment



Why Generic Markets Fail?

Interpretation Existing literature suggests three possible underlying factors

Behaviour

- Prescriber preference and brand loyalty can override price differences
- Patients may have limited information or low confidence in equivalent products

Incentives

- Supplier influence, contracting dynamics, and opaque rebates (kickbacks & discounts) can blunt competitive pressure
- Managed care tools can partially moderate price dispersion but not all utilisation patterns

Market structure

- Pseudo-generics, uneven entry, and concentrated volume shares can preserve higher-cost positions
- The result is a persistent disconnect between lower prices and actual uptake

Price regulation may shape the list price, but it does not automatically align market behaviour with policy goals

Regulatory Prioritisation Using CMDI

Application

CMDI categories are not stages, but prioritisation criteria for regulatory triage

LOW CMDI

- Markets functioning efficiently
- **Action:** Routine monitoring only - no intervention needed



MODERATE CMDI

- Potential inefficiencies detected
- **Action:** Investigate underlying drivers and market dynamics



HIGH CMDI

- Significant distortion present
- **Action:** Prioritise for regulatory review or targeted intervention



CMDI is a screening tool that informs next steps - directing limited resources to areas of greatest potential impact

How Policymakers and Healthcare Decisionmakers Can Use the CMDI Framework

Application From static price control to active surveillance



Immediate operational uses

- Prioritise therapeutic classes for deeper review
- Support formulary governance and benefit design
- Identify where generic substitution is not translating into value

Governance implications

- Improve visibility of rebates, discounts, and preferential arrangements
- Monitor prescribing and dispensing patterns where incentives may distort use
- Align policy tools across funders and levels of care

Strategic message

- CMDI is not a replacement for policy judgment
- It is an early-warning lens that helps scarce analytical capacity focus where the market looks least efficient

Concluding Message

1 | The Paradox

57%

In the national IQVIA dataset, 57% of product markets were highly distorted despite SEP and substitution rules

2 | The Contrast

24%

Schemes show fewer highly distorted markets, but volume concentration persists.

3 | The Action

CMDI

A simple composite indicator can prioritise which markets require surveillance, formulary review, and policy response

Why this matters

- Persistent misalignment between price and uptake undermines cost-effective generic use and raises pressure on affordability, scheme purchasing, and potential NHI reform
- This presentation, therefore, focused on the paradox, the magnitude, and the potential surveillance solution

Concluding Message

**Regulation is necessary.
It is not sufficient.
CMDI helps show where the market is
still not behaving as expected.**

**57% high distortion in IQVIA
24% high distortion in the
scheme claims**

**21 off-patent markets
Two independent datasets**

“The real value of CMDI is not that it explains everything, but that it gives funders and regulators a disciplined place to look first in their toolkit.”

Acknowledgements

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