

WHO Prequalification Certification and the Price–Access Trade-Off in India's Pharmaceutical Market: An Empirical Framework for Evaluating the DPCO 2013 Policy Change

Vihaan Tannan
vihaantannan10@gmail.com

ABSTRACT

India is a unique case in world healthcare because of its pharmaceutical industry. It supplies a large share of vaccines and generic medicines used across the world, but medicines are still a major expense for Indian families. This paper examines whether WHO Prequalification (PQ) certification is linked to a higher domestic price and whether the Drug Price Control Order of 2013 (DPCO 2013) changes this relationship.

We refer to this difference as the PQ price wedge. It is the difference in price between PQ-certified and non-PQ formulations of the same molecule, sold through the same market channel. To study it properly, the comparison has to be made at the brand and manufacturer level, and the price data must identify the channel in which the medicine was sold. The data must also cover a number of years before and after 2013.

The framework leads to three expectations. First, PQ certification can carry a premium because manufacturers bear additional compliance costs and because buyers may treat the certification as a sign of quality. Second, DPCO 2013 can reduce this premium only where the ceiling price actually applies and is enforced. Third, the size of the premium may not be the same for every therapeutic category, because donor demand, competition and the number of PQ-certified suppliers differ from one category to another. The paper does not treat literature-derived benchmarks as original regression results. Instead, it identifies the data and validation steps needed to estimate the PQ price wedge credibly and explains the policy implications that would follow under alternative empirical outcomes.

Keywords: WHO Prequalification, DPCO 2013, Pharmaceutical Prices, Essential Medicines, India, NPPA, PQ price wedge, access to medicines, quality certification, generic medicines, NLEM, health economics.

INTRODUCTION

The cost of using antiretroviral therapy in the mid 1990s was more than \$10,000 per year per patient, which is roughly the income per capita of most countries where HIV/AIDS was inflicting its greatest damage. It was not a breakthrough in policy in Washington or Geneva, it was a breakthrough in manufacturing capacity in Hyderabad, Mumbai and Ahmedabad.

Within a decade, generic pharmaceutical manufacturers in India were able to reduce the price of first-line ARVs to less than \$100 per person per year [1]. A large part of that story was WHO Prequalification (PQ) certification, which allowed international agencies to purchase Indian generic medicines at scale with confidence [2]. The programme was developed to solve a quality-assurance problem: how could an international buyer verify medicines from a manufacturer it did not know? It was not created as a domestic pricing tool. Even so, once a manufacturer receives PQ status, that certification can also work as a quality signal in India and may affect the price charged. This paper therefore asks whether PQ-certified medicines carry a regular domestic price premium and what DPCO 2013 does to that premium. India is an important setting for this question because its pharmaceutical sector is very large and household spending on medicines remains substantial [3], [4]. DPCO 2013 was notified on 15 May 2013 under the Essential Commodities Act 1955 and extended ceiling-price regulation to formulations listed under NLEM 2011 [13]. The study sets out the comparison and data that would be needed to answer the question without treating figures taken from earlier studies as results from the present paper.

LITERATURE REVIEW

Purpose of the WHO PQ Programme

The WHO Prequalification Programme emerged from a procurement-assurance problem rather than a domestic-market pricing problem. International agencies and low-income-country procurement bodies needed a reliable mechanism to assess the quality of medicines sourced from unfamiliar suppliers [2].

The programme evaluates products and manufacturing sites against international quality standards. Its operational importance increased when major donor-funded procurement programmes relied on PQ status as an eligibility or quality-assurance criterion. Kaplan, Wirtz, and Stephens (2013) examined generic medicine markets and quality-related market dynamics [5], while Reich and Chikuba (2008) discussed access to medicines [6]. Neither source establishes a causal domestic price premium attributable to PQ certification in India.

Quality Certification and Price Premia

Leland (1979) demonstrated theoretically that quality certification leads to producer rents, by excluding lower-cost competition from certified market segments [7]. Empirical evidence from various industries has indicated a typical range of 5–25 per cent for certification premia, with the high end being set when

the information asymmetry is large [8] (Dranove and Jin 2010).

DPCO 2013 and its repercussions

Selvaraj, Kishore and Srivastava (2014) gave the most detailed analysis of DPCO 2013, and it was concluded that the average ceiling prices were reduced by 20–30 per cent compared to the market prices before the introduction of DPCO 2013 [14]. In Maharashtra, Rane (2019) identified that the private pharmacy price always surpassed the DPCO ceiling prices, especially in rural areas [15]. Kotwani, et al. (2012) reported the private retail prices were 3–8 times higher than those of public procurement prices for the same molecules [16].

The literature therefore supports the plausibility of a certification premium, but it does not establish its magnitude in India's domestic market or show how it differs across public procurement and private retail channels.

Table 1. Structured literature review: WHO PQ, price regulation, and access

Sr.	Theme	Key Authors	Core Argument	Gap Addressed
1	PQ: Quality Origins	Kaplan et al. (2013); Reich & Chikuba (2008)	PQ improves GMP compliance	No domestic price analysis
2	PQ: Market Pricing	Yadav (2010)	PQ suppliers 15–20% premium in intl. tenders	India domestic market absent
3	DPCO 2013 Impact	Selvaraj et al. (2014)	Ceiling prices fell 20–30%	PQ × DPCO interaction unexplored
4	Public–Private Gap	Kotwani et al. (2012)	Private retail 3–8× public prices	Channel-specific PQ premium undocumented
5	Regulatory Politics	Chaudhuri (2005)	Price control reflects inter-ministry tensions	Political economy not modelled
6	Certification Premia	Leland (1979); Dranove & Jin (2010)	5–25% certification premia documented	LMIC pharma application incomplete
7	Institutional Buyers	Kremer & Glennerster (2004)	Donors prefer PQ regardless of alternatives	Export–domestic discrimination untested
8	Enforcement Gaps	Rane (2019)	DPCO ceilings regularly breached in retail	National-scale gap unmeasured
9	Credence Goods	Darby & Karni (1973); Nelson (1970)	Quality unverifiable at point of sale	No LMIC pharma domestic application

10	Generic Competition	Reiffen & Ward (2005)	Generic entry erodes prices	PQ as moderator unstudied
11	Reference Pricing	Kanavos et al. (2004)	External benchmarks constrain domestic premia	India vs. intl. PQ alignment unstudied
12	Multiple Certifications	Chaudhuri (2005); Lanjouw (1998)	USFDA may parallel PQ as domestic signal	Multiple cert interactions undocumented

TAXONOMY AND CLASSIFICATION FRAMEWORK

Defining the PQ Price Wedge

The PQ price wedge Δ_{PQ} of a molecule m in year t is defined as:

$$\Delta_{PQ,mt} = \ln(P_{PQ,mt}) - \ln(P_{nonPQ,mt}) \quad (1)$$

where $P_{PQ,mt}$ is the price of a formulation made by at least one WHO PQ-certified manufacturer and $P_{nonPQ,mt}$ is the price of the same molecule made only by non-PQ certified manufacturers. If Δ_{PQ} is positive, it means a PQ price premium.

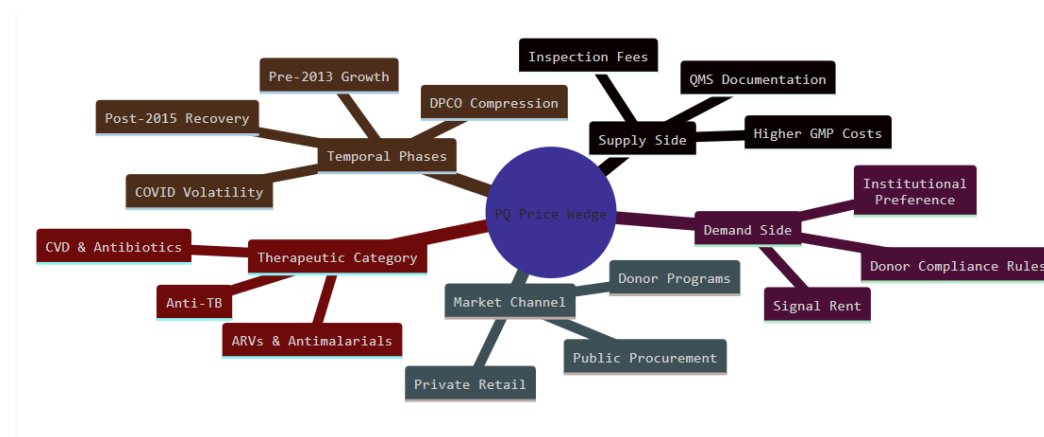


Figure 1. Conceptual taxonomy of sources of PQ price wedge along five analytical dimensions: cost drivers on the supply side, signal rents on the demand side, market channel, temporal phase, and therapeutic category.

Table 2. Sources, mechanisms, and policy modifiability of the PQ price wedge

Source	Mechanism	Expected Sign	DPCO-Modifiable?
Supply-side cost differential	GMP inputs, QMS, inspections passed to price	+	Partially
Demand-side signal rent	Institutional buyers pay above cost for assurance	+	No
First-mover advantage	Early PQ entrants capture share before competition	+	No
Certification bundling	PQ + USFDA + EU-GMP jointly command compound premium	+	No
Regulatory compression	DPCO ceilings reduce Δ _PQ when binding	–	Yes — primary
Generic competition erosion	More PQ entrants per molecule reduces per-firm premium	–	No

Market Channel Heterogeneity

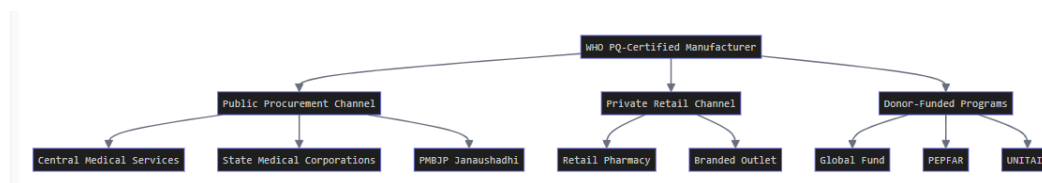


Figure 2. The system of pharmaceuticals distribution in India. Public procurement ($\approx$ 20–25% by volume (NPPA ceiling binding), private retail ($\approx$ 70–75% (enforcement imperfect), international donor programmes (Global Fund, PEPFAR, UNITAID – PQ hard eligibility gate).

Therapeutic Category Variation

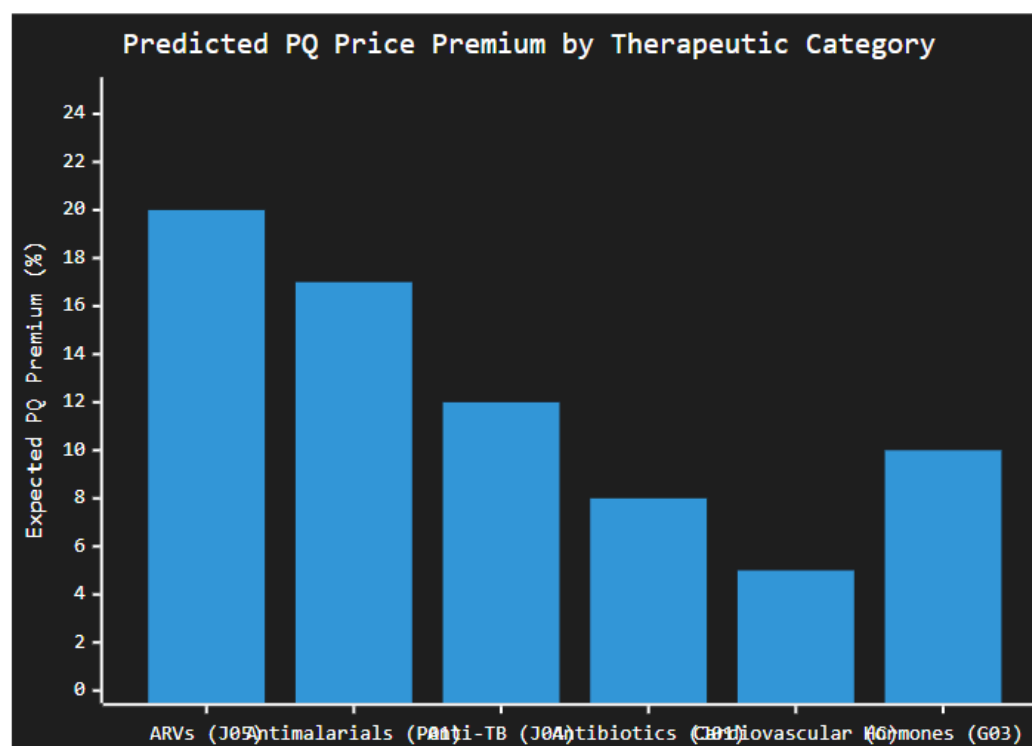


Figure 3. Price premium (+%) predicted by ATC Level-2 therapeutic category. The highest expected premiums are for ARVs (J05) and antimalarials (P01), while cardiovascular agents (C) have the lowest expected premiums.

The following table presents theoretically expected PQ premium intensities by therapeutic category. These ranges are hypotheses informed by prior literature, not estimates produced by this paper.

Table 3. Predicted PQ premium intensity by therapeutic category

Therapeutic Category (ATC L2)	Donor Salience	Generic Competition	Expected PQ Premium
Antiretrovirals (J05)	Very High	Moderate	15–25%
Antimalarials (P01)	High	Moderate	12–20%
Anti-TB Agents (J04)	High	High	8–15%
Hormones / Contraceptives (G03)	Moderate	Moderate	8–13%
Broad-Spectrum Antibiotics (J01)	Moderate	Very High	5–10%
Cardiovascular (C class)	Low	Very High	3–7%

Temporal Evolution

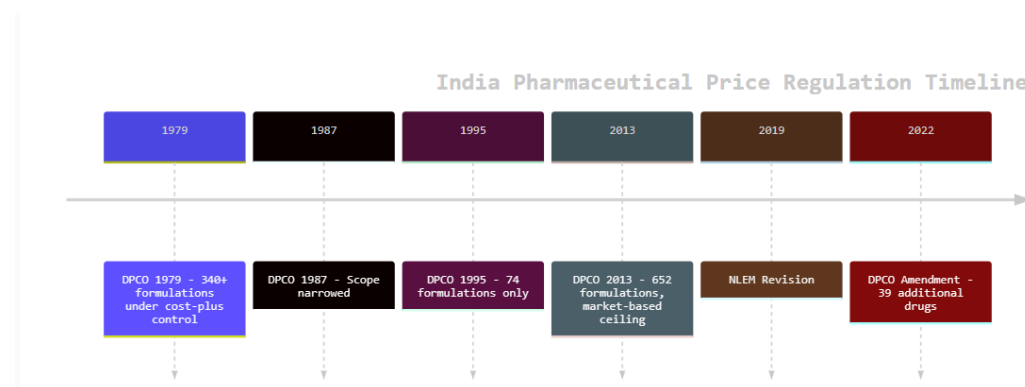


Figure 4. Milestones in drug pricing regulation in India (1979–2022), and price wedge phases. Phase I (1987–2012): pre-DPCO growth. Phase II (2013–2015): DPCO compression. Phase III (2016–2019): partial recovery. Phase IV (2020–2022): COVID disruption.

Theoretical framework

Asymmetric Information and Credence Goods

The theoretical basis comes from two familiar ideas. Akerlof (1970) showed that markets can work poorly when buyers do not have the same information about quality as sellers [17]. Darby and Karni (1973) described credence goods, whose quality is difficult for a consumer to judge even after use [18]. Medicines have this problem because a patient cannot personally check GMP compliance, ingredient purity or bioavailability. A third-party certificate can therefore separate suppliers and act as a quality signal [7]. If a PQ price wedge is found, part of it may come from the cost of meeting the standard and part may come from the value buyers place on the signal.

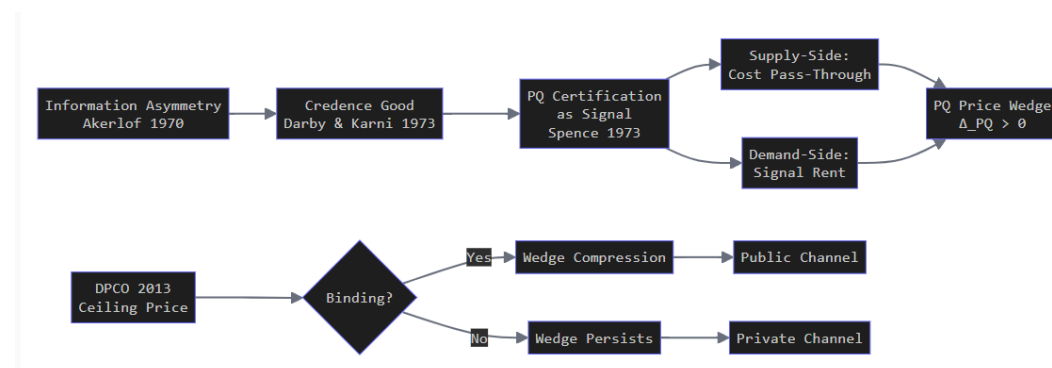


Figure 5. The framework is as follows: information about medicine quality is unequal; medicines behave as credence goods; WHO PQ provides an outside quality signal; and this may create both cost pass-through and a signal premium. The result may be a positive PQ price wedge. DPCO 2013 may reduce the wedge where the ceiling is binding and enforced, but this has to be tested from the data rather than assumed in advance.

The DPCO 2013 Ceiling Formula

The ceiling price under DPCO 2013 is calculated as follows:

$$P_{mt}^{ceiling} = \left(\frac{1}{N_m} \sum_{i=1}^{N_m} P_{imt} 1(s_{imt} \geq 0.01) \right) \times 1.16 \quad (2)$$

Here, P_{imt} is the price of brand i for molecule m , s_{imt} is its market share, and 1.16 represents the 16 per cent trade margin. If PQ brands make up most of the high-share brands, their prices will have a large influence on the average used to set the ceiling. The HHI among PQ-certified producers is:

$$HHI_{mt}^{PQ} = \sum_f s_{fmt}^2 \quad (3)$$

METHODOLOGY

Research Design

This study uses a panel design. If PQ certification is not random, DPCO 2013 is not a natural experiment without a reasonable comparison group, nor is it a natural experiment unless there is a reasonable trend in the pre-2013 data. The observation useful is the specific brand of the molecule, the specific channel, and the year in which the observation was performed. This makes it possible to directly compare PQ and non-PQ formulations of the same molecule. Features of the medicine that do not vary over time can be accounted for by a molecule fixed effect; general price changes can be accounted for by year effect; and ongoing differences in producers that are not directly explained by the product or its place of manufacture can be accounted for by a manufacturer or brand control. A causal claim can only be supported if the final data include multiple years before and after 2013 (and provide a compelling difference-in-differences comparison).

Data Requirements and Sources

The study needs five main kinds of information. First, it needs brand- or formulation-level prices for a number of years before and after 2013. Second, the PQ status of each manufacturer must be matched to the date on which the certification began. Third, every formulation must be marked as scheduled or non-scheduled under the relevant DPCO/NLEM list. Fourth, public procurement and private retail prices must come from sources that clearly identify the channel. Fifth, the data should record dosage form, strength, pack size, manufacturer, competition and other certifications such as USFDA approval. NPPA

ceiling prices are useful as regulatory benchmarks, but they are not the same as the prices actually paid by public buyers or retail patients. The WHO PQ Product List, CDSCO records, WHO EML and ATC codes, NLEM schedules and the MSH International Medical Products Price Guide can be joined to the price data as supporting sources.

Table 4. Variable definitions and measurement

Variable	Type	Definition	Source
$\ln(P_{bmct})$	Dependent	Log observed price per standard unit for brand b , molecule m , channel c , year t	Channel-specific price dataset
PQ_{bmt}	Key Explanatory	Binary: manufacturer of brand b is WHO PQ-certified in year t	WHO PQ List with dates
$Post_t$	Policy Indicator	Binary: 1 for observations after DPCO 2013 implementation	DPCO 2013 Gazette
$Scheduled_m$	Treatment Indicator	Binary: formulation/molecule covered by the relevant DPCO/NLEM schedule	NPPA / MoHFW
$Public_c$	Channel Indicator	Binary: public procurement rather than private retail	Price-source metadata
$N_{prod_{mt}}$	Control	Count of approved producers for molecule m in year t	CDSCO
$USFDA_{bmt}$	Control	Binary: manufacturer has relevant USFDA approval in year t	USFDA records
$ATC2_m$	Classification	ATC Level-2 therapeutic category	WHO ATC/DDD Index
$Ceiling_{mt}$	Regulatory Benchmark	NPPA ceiling price per standard unit	NPPA

Empirical Specifications

Baseline within-molecule association:

$$\ln(P_{bmct}) = \alpha + \beta_1 PQ_{bmt} + \gamma X_{bmct} + \delta_m + \gamma_t + \varphi_c + \mu_f + \varepsilon \quad (4)$$

DPCO difference-in-differences specification, valid only with pre- and post-2013 observations and scheduled versus non-scheduled formulations:

$$\ln(P_{bmct}) = \alpha + \beta_1 PQ_{bmt} + \beta_2 Post_t + \beta_3 Scheduled_m + \beta_4 (PQ_{bmt} \times Post_t \times Scheduled_m) + \gamma X_{bmct} + \delta_m + \gamma_t + \varphi_c + \mu_f + \varepsilon_{bmct} \quad (5)$$

Channel-heterogeneity extension:

$$\ln(P_{bmct}) = \alpha + \beta_1 PQ_{bmt} + \beta_2 (PQ_{bmt} \times Public_c) + \beta_3 (PQ_{bmt} \times Post_t \times Scheduled_m) + \beta_4 (PQ_{bmt} \times Post_t \times Scheduled_m \times Public_c) + \gamma X_{bmct} + \delta_m + \gamma_t + \varphi_c + \mu_f + \varepsilon_{bmct} \quad (6)$$

EMPIRICAL IMPLEMENTATION AND VALIDATION PLAN

Minimum Data Checks

Before running the models, every price must be matched to a manufacturer, molecule, strength, dosage form, pack size, year and market channel. PQ status must be dated; otherwise, a manufacturer may wrongly be counted as certified before it entered the programme. There must also be more than one year before 2013. Without those earlier observations, the post-policy variable does not change within the sample and the DPCO effect cannot be identified.

Required Descriptive Evidence

The first tables should show how many observations are available, where information is missing, how prices are distributed, and how often PQ and non-PQ producers appear within the same molecule. They should also show the number of scheduled and non-scheduled formulations in each year. A molecule group should not be used where there is no genuine within-molecule comparison. Public and private estimates should be shown only when the price source itself identifies those channels.

Identification and Robustness

Any interpretation of DPCO 2013 depends on the treated and comparison groups having broadly similar trends before the policy. The event-study graph must therefore be drawn from estimated coefficients rather than from an illustrative line. The checks should use different definitions of price, remove the transition year, account for other certifications, cluster the standard errors at the relevant level, and test whether the result is being driven by only a few manufacturers or therapeutic categories.

Reporting Rule

Regression tables should be added only after the linked data have been prepared and the models have actually been run. The coefficients, standard errors, p-values, number of observations and fit statistics must all come from reproducible output. Figures taken from the literature can still be used for comparison, but they must be placed in a separate benchmark table and clearly described as outside

evidence.

INTERPRETATION, POLICY IMPLICATIONS, AND LIMITATIONS

Interpreting a Possible PQ Price Wedge

A positive PQ coefficient would fit both explanations discussed above: higher compliance costs and a price paid for the certification signal. The regression by itself would not tell us how much comes from each. A result close to zero could mean that generic competition or price controls remove the premium. A negative result could occur if PQ-certified manufacturers produce at a larger scale or compete more strongly. Estimates reported for other markets [8], [9] are useful only as a point of comparison and cannot be presented as estimates from the Indian data.

Interpretation of DPCO 2013

DPCO 2013 can cause a decrease in the price wedge where the ceiling is below the price that would otherwise be imposed. That's not enough to prove that such a reduction took place since the ceiling is computed based on market prices. The analysis should be a comparison of scheduled and non-scheduled formulations both before and after the policy. It must also differentiate between the existence of a ceiling and its enforcement. This distinction is particularly relevant in the context of Rane's evidence from Maharashtra that sometimes prices have been above the ceilings set by the government in the shops [15].

Distributional Implications

This is a distributional problem only if it is observed in prices. Households purchasing medicines outside the regulated procurement system may be getting less protection than those purchasing from private retail if the PQ premium is higher in private retail. That concern is lessened if no difference is discovered. The policy argument should be based on the results of the price data, not the estimation.

CONCLUSION

This paper sets out a workable way to study the WHO Prequalification price wedge in India's domestic pharmaceutical market. The comparison must be made between PQ and non-PQ brands of the same molecule and at the brand-manufacturer level. It also explains why an NPPA ceiling price cannot, by itself, be treated as the price paid in public procurement or private retail. To study DPCO 2013 properly, the dataset needs several years before and after 2013, scheduled and non-scheduled formulations, dated PQ status and prices that identify the market channel.

The policy question is still important. The quality system that supports India's role in the pharmaceutical market may also carry a domestic price premium, and regulation may not affect that premium in the same way for every buyer. Until the required data are collected and the models are run, numerical premiums and causal effects should remain hypotheses or outside benchmarks rather than findings of this paper. In

its present form, the paper provides the empirical structure for a results paper; the results themselves must come from the completed dataset and reproducible regression output.

REFERENCES

- [1] B. Waning, E. Diedrichsen, and S. Moon, "A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries," *J. Int. AIDS Soc.*, vol. 13, no. 1, p. 35, 2010.
- [2] World Health Organization, *WHO Prequalification of Medicines Programme: Annual Report 2018*, Geneva: WHO, 2019.
- [3] World Health Organization, *The World Medicines Situation*, 3rd ed., Geneva: WHO, 2011.
- [4] National Health Accounts Technical Secretariat, *National Health Accounts Estimates for India (2018–19)*, New Delhi: MoHFW, 2021.
- [5] W. Kaplan, V. Wirtz, and P. Stephens, "The market dynamics of generic medicines in the private sector of 19 low and middle income countries between 2001 and 2011," *PLOS ONE*, vol. 8, no. 9, p. e74399, 2013.
- [6] M. R. Reich and S. Chikuba, "Improving access to medicines in developing countries," in *Working for Health*, Tokyo: Springer, 2008.
- [7] H. E. Leland, "Quacks, lemons, and licensing: a theory of minimum quality standards," *J. Polit. Econ.*, vol. 87, no. 6, pp. 1328–1346, 1979.
- [8] D. Dranove and G. Z. Jin, "Quality disclosure and certification: theory and practice," *J. Econ. Lit.*, vol. 48, no. 4, pp. 935–963, 2010.
- [9] P. Yadav, "Differential pricing for pharmaceuticals: review of current knowledge, new findings and ideas for action," UK DFID, 2010.
- [10] M. Kremer and R. Glennerster, *Strong Medicine*, Princeton, NJ: Princeton Univ. Press, 2004.
- [11] B. Waning et al., "A lifeline to treatment," *J. Int. AIDS Soc.*, vol. 13, no. 1, p. 35, 2010.
- [12] S. Chaudhuri, *The WTO and India's Pharmaceuticals Industry*, New Delhi: Oxford Univ. Press, 2005.
- [13] Ministry of Chemicals and Fertilizers, *Drug Price Control Order, 2013*, *Gazette of India*, 15 May 2013.
- [14] S. Selvaraj, P. Kishore, and A. Srivastava, "An assessment of India's new pharmaceutical pricing policy," *Lancet*, vol. 384, no. 9937, pp. 108–109, 2014.
- [15] W. Rane, "Drug price regulation in India: DPCO 2013 compliance in Maharashtra," *Indian J. Med. Ethics*, vol. 4, no. 1, pp. 24–29, 2019.
- [16] A. Kotwani et al., "Price, availability and affordability of medicines in India: a study of healthcare markets in six cities," WHO report, 2012.
- [17] G. A. Akerlof, "The market for 'lemons': quality uncertainty and the market mechanism," *Q. J. Econ.*, vol. 84, no. 3, pp. 488–500, 1970.

- [18] M. R. Darby and E. Karni, "Free competition and the optimal amount of fraud," *J. Law Econ.*, vol. 16, no. 1, pp. 67–88, 1973.
- [19] A. M. Spence, "Job market signaling," *Q. J. Econ.*, vol. 87, no. 3, pp. 355–374, 1973.
- [20] P. Nelson, "Information and consumer behavior," *J. Polit. Econ.*, vol. 78, no. 2, pp. 311–329, 1970.
- [21] D. Reiffen and M. R. Ward, "Generic drug industry dynamics," *Rev. Econ. Stat.*, vol. 87, no. 1, pp. 37–49, 2005.
- [22] P. M. Danzon and M. F. Furukawa, "International prices and availability of pharmaceuticals in 2005," *Health Aff.*, vol. 27, no. 1, pp. 221–233, 2008.
- [23] P. Kanavos et al., "The economic impact of pharmaceutical parallel trade in EU member states," LSE Discussion Paper, 2004.
- [24] J. O. Lanjouw, "The introduction of pharmaceutical product patents in India," NBER Working Paper No. 6366, 1998.