MedicalXpress

How an Indian government policy backfired: The unintended consequences of price regulation of prescription drugs

June 4 2024, by Marilyn Stone

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Researchers from the Indian Institute of Management Calcutta, University of Chicago, and Management Development Institute, Gurgaon have published a new study that examines the unintended

consequences of an Indian government health care policy.

The study, forthcoming in the *Journal of Marketing,* is titled "Do No Harm? Unintended Consequences of Pharmaceutical Price Regulation in India" and is authored by Saravana Jaikumar, Pradeep K. Chintagunta, and Arvind Sahay.

In countries without universal health insurance or developed health care systems, governments try to make drugs affordable and accessible. For instance, in India, where around 80% of health care expenses are borne privately with the majority paid out-of-pocket, the ostensible reason for price regulation is to increase the affordability of essential drugs. However, there is a general lack of empirical evidence assessing the impact of regulation on the availability, accessibility, and sales of prescription drugs in emerging economies, such as India.

This new study examines the unintended consequences of India's Drug Price Control Order in 2013 (DPCO 2013) that was instituted to make essential medicines more affordable. Because of the lower prices intended to increase drug accessibility, the researchers find that pharmaceutical firms curtailed marketing efforts for regulated drugs due to diminished profit margins and shifted their focus to unregulated (but related) drugs. This shift disproportionately affected prescriptions issued by less formally educated physicians—those who often serve the most economically disadvantaged populations, and the very groups DPCO 2013 aimed to benefit.

The process began in September 2011 when the Indian government prepared a National List of Essential Medicines (NLEM). In May 2013, the government announced price regulations for these drugs, capping their prices. Brands priced above the cap were required to reduce their prices to at or below the price cap, while brands already priced below the cap were required to retain current prices.

The government implemented several measures to mitigate potential negative reactions from firms. The order required firms to maintain current production volumes of regulated drugs. While firms may apply to exit a category with a six-month notice, the order reserved the right to mandate production for up to 12 months. Furthermore, price increases for regulated drugs were limited to inflation levels. Additionally, it capped annual price hikes for unregulated drugs at 10% to prevent firms from offsetting lost margins on regulated drugs by raising prices on unregulated ones.

The marketing curveball

The researchers looked at 179 oral solid drugs (pills) included in DPCO 2013. By comparing data from India to the Philippines—a country without similar regulations—they found that on average, the sales volumes of these regulated drugs declined in India.

The strategic shift in marketing efforts of firms is identified as a main contributing factor. In India, where direct-to-consumer advertising is prohibited for prescription drugs, the main vehicle for promotion is detailing; that is, providing information about drugs and their efficacy to physicians, usually by medical representatives from pharmaceutical firms. Jaikumar says that "using detailed data from a large pharmaceutical firm, we find that due to the lowered margins of regulated drugs, firms shifted their detailing focus to unregulated but related drugs. For example, a firm could have shifted its marketing focus from atorvastatin, which is a regulated drug for cholesterol issues, to rosuvastatin, an unregulated drug prescribed for similar issues."

The study further examines this shift's impact on prescriptions from physicians without formal medical degrees (termed as non-MBBS Physicians). Large parts of India lack access to highly qualified doctors, and physicians without formal medical degrees usually provide health

care and actively prescribe allopathic medicines.

"Due to the shift in detailing focus, the percentage of prescriptions for regulated drugs from these non-MBBS physicians declined. Further, our surveys show that compared to formally trained medical professionals, non-MBBS physicians relied heavily on pharmaceutical detailing to inform their prescribing practices," explains Chintagunta.

The research rules out other potential explanations for the declining sales volumes of regulated drugs. The prevalence of diseases like acute respiratory infections, circulatory system diseases, diabetes, HIV/AIDS, malaria, and pneumonia has increased, which does not explain the sales decline. Also, new drug approvals have dropped significantly since 2013 and AYUSH (traditional Indian medicine) has also declined.

"Our findings strongly support a detailing-led explanation for the reduced sales volumes," says Sahay.

Lessons for regulators, marketing officers, and advocacy groups

This study serves as a reminder of the interconnectedness of policies and market dynamics.

- Regulators must understand the full spectrum of a policy's impact before implementing it. This includes considering how pharmaceutical firms might react to price caps, including marketing strategies, and the downstream effects on health care providers and patients.
- Pharmaceutical companies need to maintain a balance between profitability and social responsibility, particularly in markets heavily reliant on out-of-pocket spending for health care.

- Patient advocacy groups must amplify their role in policy discussions, ensuring that the voices of the most vulnerable populations are heard and that their needs are prioritized in health care regulations.

More information: Saravana Jaikumar et al, Do No Harm? Unintended Consequences of Pharmaceutical Price Regulation in India, *Journal of Marketing* (2024). DOI: 10.1177/00222429241242685

Provided by American Marketing Association