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Doctors' Awareness of DPCO Bypassing and Availability of Single-Molecule Antibiotics: A Cross-Sectional Survey

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ABSTRACT

The Drug Price Control Order (DPCO) in India aims to improve the affordability of essential medicines. However, the extent to which practising doctors are aware of pharmaceutical strategies used to bypass DPCO and the real-world availability of single-molecule DPCO-controlled antibiotics remains unclear. This cross-sectional survey was conducted exclusively among doctors, including General Practitioners, Dermatologists, Surgeons, and Gynaecologists. The questionnaire assessed awareness of DPCO, awareness of bypassing practices, and doctors' experiences regarding the availability of single-molecule antibiotics such as doxycycline HCl 100 mg. The findings revealed that most doctors were unaware of pharmaceutical practices used to bypass DPCO price controls. A small proportion of doctors who were aware reported significant difficulty in obtaining plain single-molecule DPCO antibiotics from pharmacies, which preferentially stocked combination formulations. Some respondents reported that strict insistence by the prescribing doctor was often required to ensure

the availability of single-molecule DPCO medicines for patients. The study highlights a gap between DPCO policy intent and on-ground medicine availability, driven primarily by limited awareness among doctors and pharmacy-level stocking practices rather than prescriber intent.

KEYWORDS: DPCO (Drug Price Control Order), Antibiotic Availability, Pharmaceutical Formulation Bypassing, Doctors' Awareness, Price Control Consequences.

INTRODUCTION

Drug Price Control Order (DPCO) is an important regulatory tool in India where the prices of the necessary medicines are aimed to be controlled to make them affordable to the citizens. According to DPCO, which was introduced in 1970 as a provision of the Essential Commodities Act, the body is meant to regulate the prices of commodities that are essential to the health of the population and therefore allow people to have access to affordable treatment (Patil and Stephen, 2025). Nevertheless, regardless of the good influence that it has in lowering the price of the necessary drugs, DPCO has received criticism that has led to undesired effects, particularly in the pharmaceutical sector. Although DPCO has assisted in making medicines more affordable, the unforeseen consequence is that it has also caused physicians to experience some problems when trying to gain access to the single-molecule antibiotics in which DPCO has gained control over since the pharmacy level. Such a phenomenon not only compromises the efficacy of treatment but also casts doubt on the overall consequences on the health of the population (Luiza et al., 2015).

As Atella et al. (2012) observe, although price control is necessary in the regulation of drug prices, the unanticipated effects of this control include the added ingredients or changes, which are not clearly scientifically-supported. As an example, the pharmaceutical firms may incorporate some ingredients in antibiotics like Lactobacillus in Doxycycline, which may be sold as a way of improving therapeutic value without any clinical benefit. While formulation modifications are often presented as patient-centric improvements, evidence suggests that such delivery-oriented changes do not always translate into meaningful clinical benefit (Baryakova et al., 2023; Stewart et al., 2024).

This is not the only case where price controls led to a modification in the formulation of drugs. A study by Pantoja et al. (2022) revealed that the same price controls had led to the presence of non-therapeutic substances to lower the overall price of drugs, thus avoiding the regulatory barriers. Moreover, Schweitzer and Lu (2018) added that price control mechanisms are designed to reduce the costs of healthcare, but in most cases result in unintended outcomes, such as the change of the drug formula, as companies are trying to keep their profits despite the price control requirements. The changes can result in products that fall short of the needed standards of clinical efficacy, thereby endangering the well-being of the consumers they are meant to safeguard.

The regulatory environment of DPCO has been experiencing growing criticism. Although it has succeeded in making necessary drugs affordable, it has not been without its problems. This confusion has given an opportunity to pharmaceutical corporations to bring poorly justified formulations under the pretext of therapeutic enhancement. Ongoing expert discussions in recent scientific and policy forums have emphasized the importance of strengthening regulatory oversight mechanisms to prevent unintended consequences of price control measures (ACNP, 2024). This research seeks to investigate the degree to which DPCO has resulted in the alteration of antibiotic formulations and how such alterations are threatening the scientific formulations. The study will evaluate the DPCO awareness on the purpose and unwanted implications of drug formulations by analyzing the perception of the pharmaceutical professionals and health professionals. Another issue that the research will explore is whether the changes are mainly influenced by commercial interests or clinical gain, which will offer valuable information on the possibility of health risks arising due to these changes.

Research results of this study will be of great impacts to the policy makers and regulators. Although DPCO has worked effectively in bringing down the drug prices, there have been unintended side effects of potentially irrational formulations, which question the long-term effectiveness of the DPCO. The policymakers should look into reinforcing laws, which directly touch on altering the formulations

of drugs to make sure that it does not infringe on the health of the people. The research will also play a role in the current debate concerning the weaknesses and inefficiencies of price control instruments and contribute to the process of informing the changes in policy in the future to make sure that the implementation of drug price controls does not compromise the quality of medications available to the population.

Further studies in the given direction should be aimed at longitudinal research to determine the long-term impacts of DPCO on drug formulation and the health outcomes of the population. Moreover, a discussion of the regional variations in the application of price controls and their difference in the quality of drugs would prove to be informative with respect to the same price regulations impacting the pharmaceutical activity in other environments. It should also be researched whether the stricter regulatory frameworks can be effective and can be used to prevent the spread of irrational formulations and the affordability of the necessary medicines.

Although there are increased debates regarding formulation modifications, there is very little information on the extent to which practising doctors are knowledgeable of such pharmaceutical measures. Also, despite the efforts by doctors who seek to prescribe the single-molecule DPCO-controlled antibiotics, the situation in practice at the drug dispensing level remains unclear. This is needed to know the awareness of doctors and their experience of accessing plain DPCO medicines to test whether difficulties encountered are due to prescriber behaviour or supply-chain and stocking practices.

Objectives of the Study

1. To determine the degree of enlightenment of doctors on the Drug Price Control Order (DPCO) and pharmaceutical approaches towards avoiding price controls.
2. To assess the experiences of doctors concerning the availability of the single-molecule DPCO-controlled antibiotics, e.g. doxycycline HCl 100 mg, at the pharmacy level.
3. To determine the perceived obstacles that doctors encounter in making plain DPCO medicines available to the patients.

METHODOLOGY

Research Design

The research design was a quantitative cross-sectional survey design used to evaluate the awareness of doctors about the Drug Price Control Order (DPCO) and the experiences of the doctors associated with the availability of single-molecule DPCO-controlled antibiotics. The research concentrated on the view of prescribers and not the manufacturing practice. Information about awareness regarding DPCO, awareness regarding bypassing practices, and existing practical issues encountered when making a prescription were collected on a structured questionnaire.

Study Population

The population sample was restricted to only practicing medical doctors that included General Practitioners, Dermatologists, Surgeons and Gynaecologists. Registered doctors who are actively engaged in patient treatment and antibiotics prescribing were used only. The study excluded pharmacists, pharmaceutical industry staff, regulatory agents, students, interns and non-clinical staff.

Sampling Method

The stratified sampling method was adopted to incorporate the doctors of four clinical specialities: General Practice, Dermatology, Surgery, and Gynecology. A sample size of 300 doctors was used, as it was expected to represent a sufficient number of doctors in any specialty. Hospitals, clinics and private practices in various parts of India were used to recruit the participants.

Data Collection Procedure

Both online and offline modes were used to collect the data to be used in the study. The online survey was sent to a vast number of respondents through email, whereas the offline survey was carried out through real-life interaction. The multimodal strategy increased accessibility in various regions and professional fields. The survey was carried out in 3-4 weeks. Before mass distribution, a pilot test was done on a limited sample of 10-15 individuals to make some adjustments on the questionnaire to make it clearer and more accurate on the survey items. The study strictly followed ethical standards and informed consent of all the participants was provided. The consent form provided the aims of the study, the voluntary participation, and the anonymity of the feedback. The respondents were notified that they could quit the study at any point and there would be no repercussions.

Ethical Considerations

The study adhered to established ethical standards. All participants were informed about the objectives of the study, the confidentiality of their information, and the voluntary nature of participation. Participation was undertaken only after informed consent was obtained from all respondents. The study ensured the anonymization of participant data and did not disclose any personal information without explicit consent. Furthermore, participants were permitted to withdraw from the study at any stage without any adverse consequences.

Data Analysis

Descriptive statistics were used to analyse the survey data and summarise the results, including means, frequencies, and percentage distributions for Likert-scale items. The analysis aimed to examine participants' perceptions regarding the influence of the Drug Price Control Order (DPCO) on antibiotic preparations and the challenges encountered in complying with regulatory requirements. Inferential statistical methods were employed to assess potential relationships between awareness of DPCO and perceptions of irrational antibiotic formulations. The review was aimed at defining the awareness rates among physicians and outlining the trends connected with the unavailability and prescribing difficulties related to medicines controlled by DPCO.

RESULTS

Awareness of DPCO and Bypassing Practices

The results indicated that most physicians were aware of the general aim of DPCO in the control of the medicine prices but most of them were not familiar with the pharmaceutical practices of avoiding pharmaceutical price-controlling rules of DPCO. Web 2 Knowledge- knowledge of the respondents who had knowledge of formulation-based bypassing strategies was not high, which means there is knowledge gap among the prescribers regarding such practices.

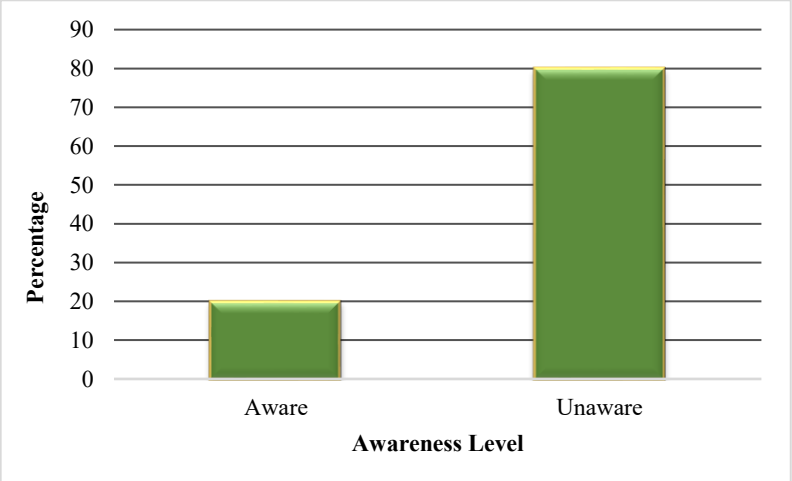


Figure 1: **Awareness Level of Doctors Regarding the DPCO and Bypassing practices**

Availability of Single-Molecule DPCO Antibiotics

Physicians who knew about DPCO bypassing procedures complained that they found it extremely hard to find single-molecule DPCO-modified antibiotics in pharmacies. One common example that was mentioned was that of doxycycline HCl 100 mg and it was reported that this was not often available even with a prescription. The respondents also observed that pharmacies were selective in filling combination formulations and discouraging the dispensing of plain single-molecule antibiotics.

Perception of DPCO's Impact on Formulations

The study sample was presented in Figure 2 and it illustrates the doctor specialties. It gives us information about the professional background of the respondents to the study as well as that the perceived attitudes of the respondents to DPCO and their implication on the availability of single-molecule DPCO-controlled antibiotics in practice is put into perspective.

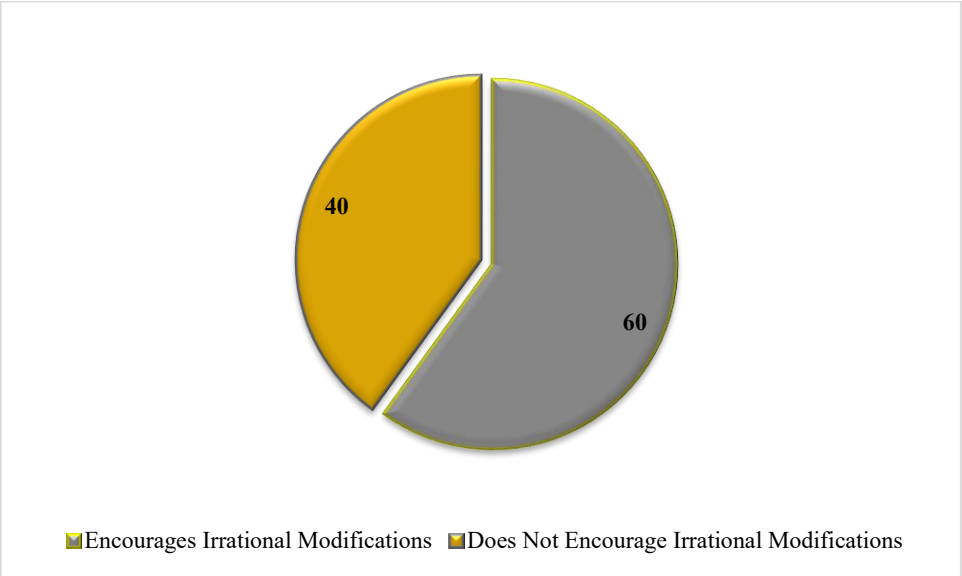


Figure 2: **Distribution of Roles Among Doctors**

Impact of DPCO on Antibiotic Availability

The major section of the questionnaire was built on the investigation of the availability of the single-molecule DPCO-regulated antibiotics and the challenge physicians face due to the limitations on the pharmacy level. The findings have revealed that most physicians cannot find plain single-molecule DPCO-controlled antibiotics due to the pharmacies having combinations formulations. In particular, 55 percent of physicians reported that pharmacies are more willing to stock combination as opposed to the single-molecule DPCO medications like doxycycline HCl 100 mg that comprise of doxycycline and lactobacillus combinations.

The scientific validity of such form of modifications is doubted by most doctors even though pharmacies are inclined to justify it by the aspect of therapeutic usefulness. The prescribing doctor may need to insist that the single-molecule DPCO medicines be available, as reported by the respondents.

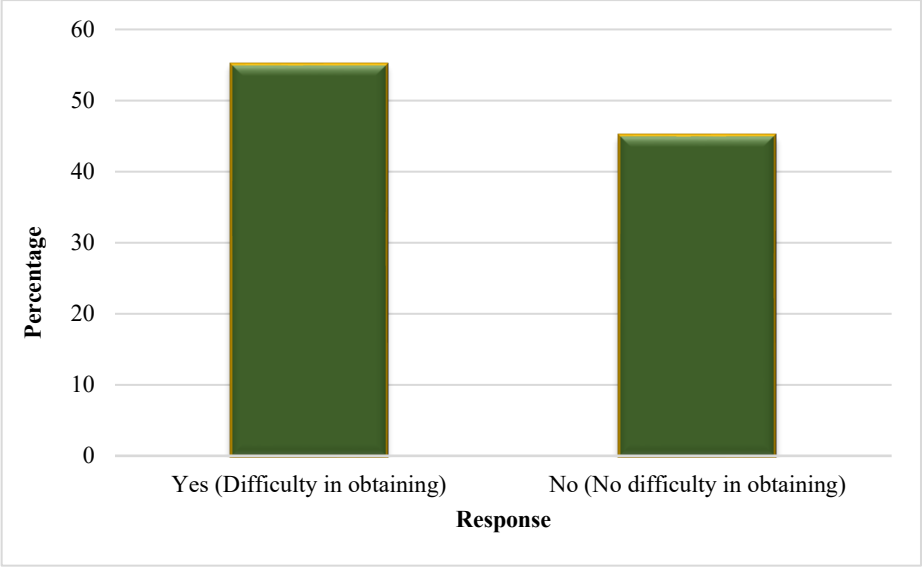


Figure 3: Impact of DPCO on Antibiotic Availability

Perception of DPCO's Impact

Majority of the respondents (68) thought that they were more of a commercial drive than a genuine clinical benefit, as witnessed in Figure 4. This led to the great issues of potentially false advertisement processes whereby the added ingredients are promoted as therapeutic value which is claimed despite the fact that such claims have been made without scientific evidence.

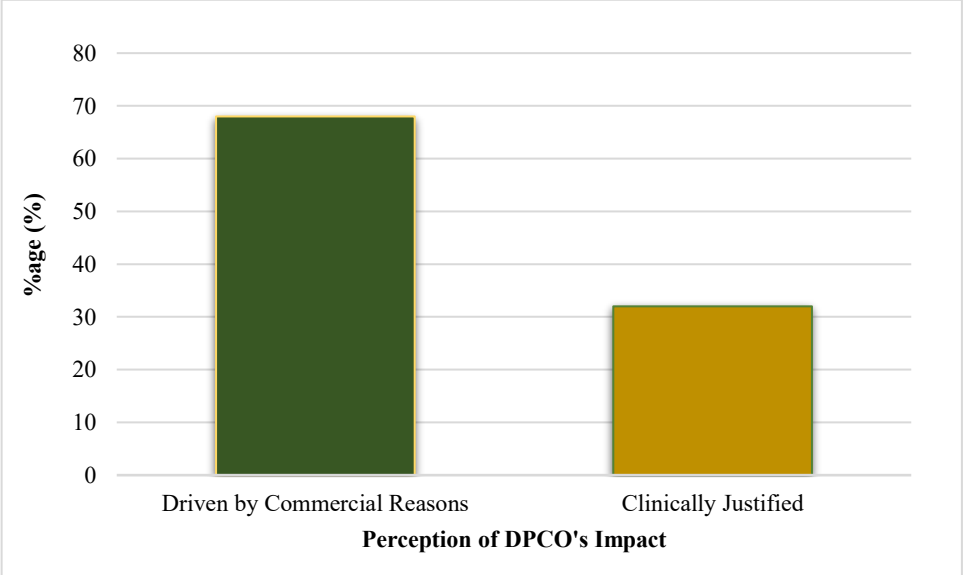


Figure 4: Perception of DPCO' s Impact

Comparative Market Pricing of Doxycycline Formulations

The pricing differences between doxycycline monotherapy and doxycycline-lactobacillus fixed-dose combinations are offered in the Indian market. Figure 5 offers contextual market data, which can be used to interpret the formulation modification and pricing behaviour under the regulations of Drug Price Control Orders.

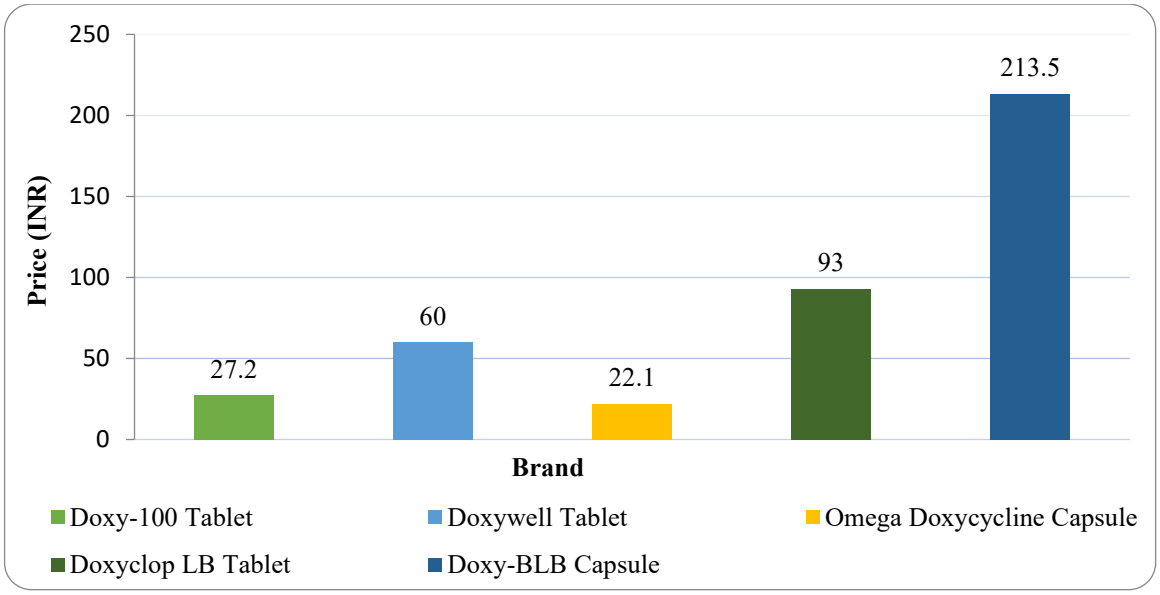


Figure 5: Comparative Market Prices of Doxycycline Formulations

Note: Prices represent indicative retail listings from publicly accessible Indian pharmacy websites (PharmEasy, Zenerics, 1mg). Values may vary by brand, dosage strength, retailer, and time of access.

Statistical Test Results

Perception of DPCO's Effectiveness Across Different Doctor Specialities

The application of DPCO to different types of specialties of the doctor (General Practitioners, Dermatologists, Surgeons, and Gynaecologists) was compared in terms of their perceived efficacy that was aided by a One-Way ANOVA. The result showed that there was no significant difference in perceptions of the specialities as concerns perceptions of DPCO effectiveness (Figure 6). This F-value was 0.36 and p-value of 0.95 is above 0.05. This demonstrates the fact that, speciality of the doctor is not a significant factor when it comes to the impression regarding the efficacy of the DPCO.

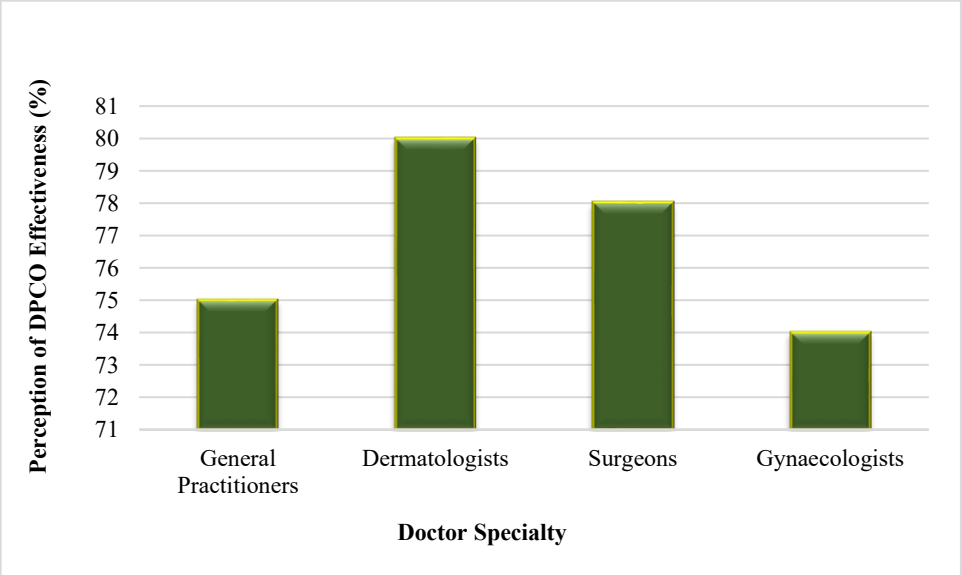


Figure 6: Perception of DPCO Effectiveness (%)

Chi-Square Test Results: Doctor Specialities vs. Awareness of DPCO and Pharmacy Constraints

The identification of the influence of the doctor specialities (General Practitioners, Dermatologists, Surgeons and Gynaecologists) and whether the DPCO was aware of the practice and experiences of

the pharmacy level constraints of availability in bypassing the practices (Table 1) was done using Chi-Square Test of Independence. The findings were that even though no significant relationship was found between doctors speciality and their awareness on DPCO bypassing practice, there existed a tremendous variance as far as pharmacy constraints were concerned.

Table 1: Chi-Square Test Results for Doctor Specialities vs. DPCO Awareness and Pharmacy Constraints

Test Factor	Chi-Square Statistic	P-value	Interpretation
Doctor Specialty vs Awareness of DPCO	4.12	0.053	No significant relationship between doctor speciality and awareness of DPCO bypassing.
Doctor Specialty vs Pharmacy Constraints	6.34	0.022	Significant relationship between doctor speciality and pharmacy-level constraints.

Comparison of DPCO's Effectiveness Based on Doctor Specialties

The Kruksal-Wallis H Test was employed to examine the perception of the effectiveness of DPCO between the specialities of doctors (General Practitioners, Dermatologists, Surgeons, and Gynaecologists). The purpose of analysis was to know whether the specialties of doctors affected their vision of the effectiveness of DPCO and the resistance they encounter at the pharmacy level. The results showed that the perceptions of the effectiveness of DPCO did not differ significantly regarding the different doctor specialities (Table 2). Nevertheless, the major differences appeared in the comparison of the pharmacy-level limitations faced by doctors with varied specialties.

Table 2: Kruskal-Wallis H Test Results for Perception of DPCO's Effectiveness

Factor	Test Statistic	P-value	Interpretation
Doctor Specialty (GP, Dermatologist, Surgeon, Gynaecologist)	2.45	0.102	No significant difference in perception based on specialty.
Pharmacy-level Availability Constraints	3.89	0.03	Significant difference in pharmacy constraints across specialties.

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DISUSSION

These findings imply that awareness on the practice of bypassing practices of DPCO by doctors is usually low. In even conscious individuals, there are huge obstacles at the pharmacy level, whereby the single-molecule-DPCO-controlled antibiotics are not always found. Pharmacies generally focus more on combining products and thus it becomes hard to keep their patients under the right DPCO drugs. Nevertheless, although there was this awareness, a significant gap in the perception of the wider regulatory implications of DPCO was observed, with half of the respondents having an in-depth comprehension of its effects in the long-term on the pharmaceutical practice and market dynamics. Such perceptions raise broader concerns regarding marketing practices and the need for clearer regulatory scrutiny of formulation claims. This implies that although the short-term goals of DPCO are well known, the implications are not well established among a large percentage of the industry professionals, which may obstruct the effective implementation and adherence to the policies.

The implications of the findings infer that there is a low awareness of DPCO bypassing practices among the doctors. There are still significant obstacles on the level of pharma-care, where single-molecule DPCO-controlled antibiotics cannot be bought even by those who are conscious. The majority of pharmacies are usually concerned with combination products and doctors will struggle to

ensure their patient takes the right DPCO medicines. This outcome highlights one of the central issues the literature has raised in regard to price control, namely, the fact that it can lower the prices to a point that motivates unsound practices in drug manufacturing. Doctors were reported to be a major obstacle in pharmacy practices such as using combination formulations over single-molecule DPCO-controlled antibiotics, even when the doctors were aware of the practices of DPCO bypassing. This has been an increasing issue, as it not only impacts the therapeutic effect of medicines but can lead to deceptive marketing practices, which purport therapeutic effects to a product when none exist. The results of the present research, indicating a 55 % change rate in the pharmacological formulations, are consistent with the existing literature that has found that the same trends have been noted in the pharmaceutical industry (Savla et al., 2017; David et al., 2015). The results are in line with the past studies that have pointed out the unintended effects of drug price control policies. All the studies by Vora et al. (2023), Luiza et al. (2015) have indicated that price caps, although effective in lowering the cost of necessary drugs, may result in the alteration of the current formulations in non-scientifically justifiable ways. Similar observations in earlier studies indicate that price control regulations may unintentionally encourage formulation modifications lacking clear therapeutic justification, consistent with evidence that pricing frameworks influence pharmaceutical market strategies (Cassier, 2021). This may reflect adaptive market behaviour under price regulation, as perceived by study participants, by adding non-therapeutic components, which might not have clinical value, but ensure that the product will not be out of the market due to the price restriction. The same results are supported by the works of Martin and Jegasothy (2025) and Li et al. (2025), who add that the strategic incorporation of supplementary components to enhance perceived product value without proportionate functional benefit has also been reported in other regulated formulation-based industries.

Comparing the present research with the past researchers, it is evident that although there have been many studies on the economic impact of price controls on the pharmaceutical industry, very few studies have addressed the unintended consequences of price controls, like changes in the formulations and implications of the change on consumer safety (Lu, 2018). Mokaddas et al. (2025) point out that although price controls are beneficial in that they make drugs affordable to the population, they can also contribute to the fact that the overall quality of drugs will decrease. Concerns regarding quality compromise under regulatory or cost-containment pressures have been documented across multiple public health domains, highlighting the need for safeguards that extend beyond affordability alone (Olney et al., 2023). Defining rationality in pharmaceutical formulations remains complex, particularly when formulation modifications are justified on technological or delivery-related grounds rather than direct therapeutic necessity (Desai et al., 2023). The results of the study indicate that commercial interests tend to override clinical reasons in the context of changing the formulations based on DPCO.

The implications of the study for policymakers and the doctors are high. First, it implies that the existing regulations of DPCO are effective in reducing drug prices but do not necessarily take into account the long-term consequences of their effects on drug formula integrity. The observation that two out of three people are of the view that change is encouraged more by business than by patient necessity is evidence of the necessity of guidelines that are clearer to avert the misuse of the price control. The fact is that it is strongly expected that there should be much more stringent regulation controls over the fact that the change of formulations to which they make is really scientifically justified and that it is really good for the patients. Regulating bodies should provide clearer requirements on what should be deemed as acceptable drug formulation changes.

Besides, the research shows that the knowledge of DPCO and its consequences is still unproductive among a significant number of industry professionals, which makes it necessary to introduce extensive education and training courses. Such programs will be supposed to give a more thorough insight into DPCO, and the possible unintended effects of its price control measures. The DPCO might become more successful in reaching its objectives without causing distortion of the market and disruption of

the quality of the drugs in the industry by enhancing the industry awareness of the larger regulatory frameworks.

Nevertheless, this research is limited in a number of ways. First, the sample might not be fully representative of the whole population of pharmaceutical professionals, and they might give biased responses due to self-reports. The research also depended on self-reported information of the participants regarding their perceptions of DPCO and its impacts, which may be affected by personal opinion or lack of exposure to certain regulatory aspects. Also, the study had not taken into account regional differences in the effects of DPCO, which may influence the perception and experience of various regions of the country to the unintended consequences of price controls. Future research ought to include a more diverse and bigger sample and look at the variation in the effect of DPCO on the pharmaceutical market across regions.

To sum up, although DPCO is important in terms of controlling the affordability of basic medicines, its unintended consequences, including formulation modifications, deserve a serious challenge. This study indicates that the regulatory watch over the development of formulation products must be more rigorous and explicit on the alterations to the formulations to avoid the quality of the drugs being compromised. Addressing the problems will help DPCO to align better with its desired and intended goals of promoting the health of the population and upholding the integrity of pharmaceutical products. More studies and policy modifications are required to make sure that the benefits of DPCO are optimized without accidental creation.

CONCLUSION

The research determines that although DPCO is very important in regulating drug prices, a major percent of doctors is not aware of the pharmaceutical methods to evade DPCO regulations. Even people that are conscious of such practices are at a big disadvantage of making sure that their patients are being given single-molecule DPCO-managed antibiotics. These obstacles are due to availability limitations on a pharmacy level and not intent to prescribe. The results reveal that, although a sizeable percentage of the respondents (75 %) realizes the main goal of DPCO to regulate the prices of drugs, only half are certain about the extent of its rules, including its long term importances to pharmaceutical operations. Also, 60 % of respondents found that price caps indirectly stimulate the formulation change, and Lactobacillus is a popular non-therapeutic supplement to antibiotics. This casts doubts on the business interests of such changes, which tend to prevail over clinical advantages. Moreover, statistical tests, such as the Independent T-test, One-Way ANOVA, and Kruskal-Wallis H Test, did not indicate any significant difference in the perceptions of the effectiveness of DPCO depending on the factors such as the level of experience and the size of the company and therefore other variables might have a more significant influence on the perceptions towards the effects of DPCO. The findings indicate that price control regulations may unintentionally be associated with formulation modifications that raise concerns regarding therapeutic justification and rational antibiotic use. In the development of longitudinal studies, additional studies ought to be conducted on future research to determine the long-term impact of DPCO on the drug market and quality. Research done on the regional differences in the effects of DPCO and how stronger regulatory systems would be would give good information on how regulatory policies can be perfected. The necessity of future research lies also in the exploration of the possible innovative pricing models that will help to balance the affordability and maintainability of the quality of drugs, so that DPCO will be able to achieve its public health goals without affecting the effectiveness of drugs.

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