AN EVALUATION OF INDIAN MEDICAL DEVICE INDUSTRY'S EXPOSURE TO PRICE CONTROL REGULATION

A Presentation

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INTRODUCTION

- **The Drugs (Prices Control) Order, 2013** empowers the NPPA to regulate prices of essential medicines on the NLEM, aiming to ensure affordability, availability, and rational use of drugs in India.

➢ <u>Objectives of DPCO, 2013:</u>

i. Increase price-controlled drug formulations from 74 to 652 and ensure their affordability.
ii. Regulate prices of 348 essential medicines, promote rational use, and ensure availability of quality drugs at reasonable prices.

- **National Pharmaceutical Pricing Authority (NPPA)** is an independent regulator ensuring fair drug pricing and accessibility, enforcing the Drugs (Prices Control) Order and monitoring pharmaceutical availability, while providing advice and support to the government on drug policy and price-related matters.

➢ <u>Functions of NPPA:</u>

i. Enforce the provisions of the Drugs (Prices Control) Order and handle related legal matters.
ii. Monitor pharmaceutical availability, address shortages, gather data on production and market shares, conduct cost-related studies, provide advice on drug policy, and support government inquiries on drug prices.

सत्यमेव जयते

NPPA

AFFORDABLE MEDICINES FOR ALL

- **Medical Device Regulation in India:**

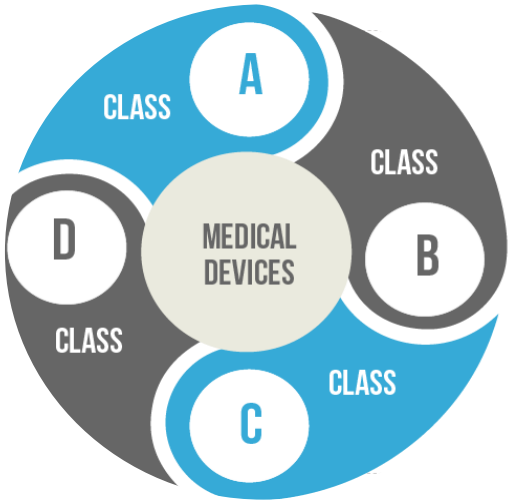
i. The Medical Devices Rules, 2017 and the Medical Device (Amendment) Rules, 2020 provide the regulatory framework for medical devices in India.

ii. The Central Drugs Standards Control Organisation (CDSCO) and the Drug Controller General of India (DCGI) regulate the production, importation, sale, and distribution of medical devices under the 1940 Drugs and Cosmetics Act.

- **Medical Device Rules, 2017:**

i. The Medical Devices Rules, 2017 set the standards for clinical research, manufacturing, importation, marketing, and distribution of medical devices in India.

ii. The rules include device classification based on risk, a single-window web portal for registration and review, indefinite validity of manufacturing and import licenses, and specific regulations for clinical investigation of new devices.



- **Medical Device Definition as per MDR 2017:**

i. Medical devices encompass substances used for in vitro diagnosis, surgical dressings, contraceptives, disinfectants, and devices notified by the government.

ii. In vitro diagnostic medical devices (IVDs) are substances used for in vitro diagnosis.

- **Risk-Based Classification of Medical Devices:**

i. Medical devices are classified into four risk classes (A, B, C, D) based on associated risks.

ii. There are a total of 347 medical devices classified across the four risk classes

- **Medical Device (Amendment) Rules, 2020:**

i. The Medical Device (Amendment) Rules, 2020, were introduced as an amendment to the Medical Devices Rules, 2017.

ii. These rules, effective from April 1, 2020, define a new category of medical devices and require mandatory registration for all medical devices.

iii. The amendment brings medical devices under the purview of the pharmaceuticals and Cosmetics Act of 1940, subjecting them to the same regulations as pharmaceutical products.

- **New Medical Device Definition:**

i. The amended rules provide a comprehensive definition of medical devices, including instruments, appliances, implants, materials, software, and accessories intended for human beings or animals.

ii. The definition encompasses devices used for diagnosis, prevention, treatment, monitoring, support, investigation, disinfection, and control of conception.

iii. All medical devices sold in India are now governed by the 1940 Drugs and Cosmetics Act.

- **Changes Introduced by Medical Device (Amendment) Rules, 2020:**

i. The amendment introduces a new chapter for the registration of medical devices by manufacturers and importers.

ii. It also exempts 37 categories of currently used medical devices from the registration requirement if they are regulated or notifiable.

- **Medical Devices Price Control Regulation in India:**

i. In February 2020, the Ministry of Health and Family Welfare expanded the definition of "drugs" to include all medical devices sold in India, subjecting them to price control regulation.

ii. Previously, only 37 registered medical device categories were under price control regulation.

iii. The National Pharmaceutical Pricing Authority (NPPA) is responsible for monitoring and regulating the pricing of medical devices.

- **Approaches Used by NPPA for Price Control:**

i. Ceiling Price Fixation (Price Capping): NPPA sets a maximum price (ceiling price) for certain medical devices.

ii. Trade Margin Rationalisation (TMR): TMR involves capping the trade margin, which is the difference between the maximum retail price and the price at which manufacturers sell devices to distributors.

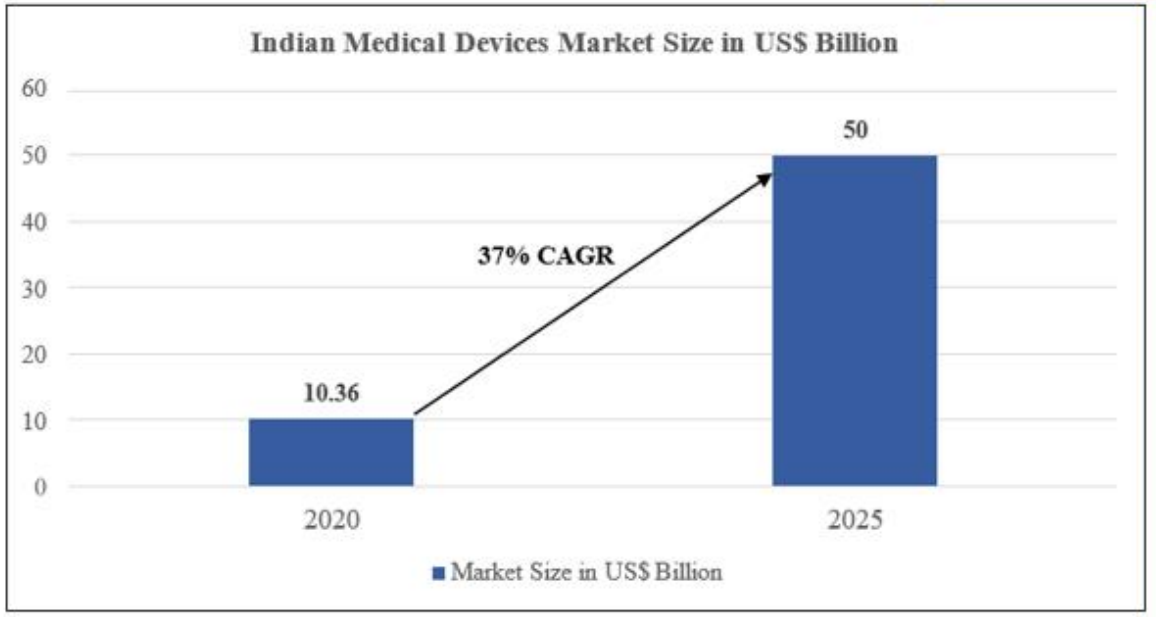
- **Calculation of Maximum Retail Price (MRP) under TMR:**

NPPA uses the following formula: **MRP = PTD + (PTD × TM) + Applicable GST**

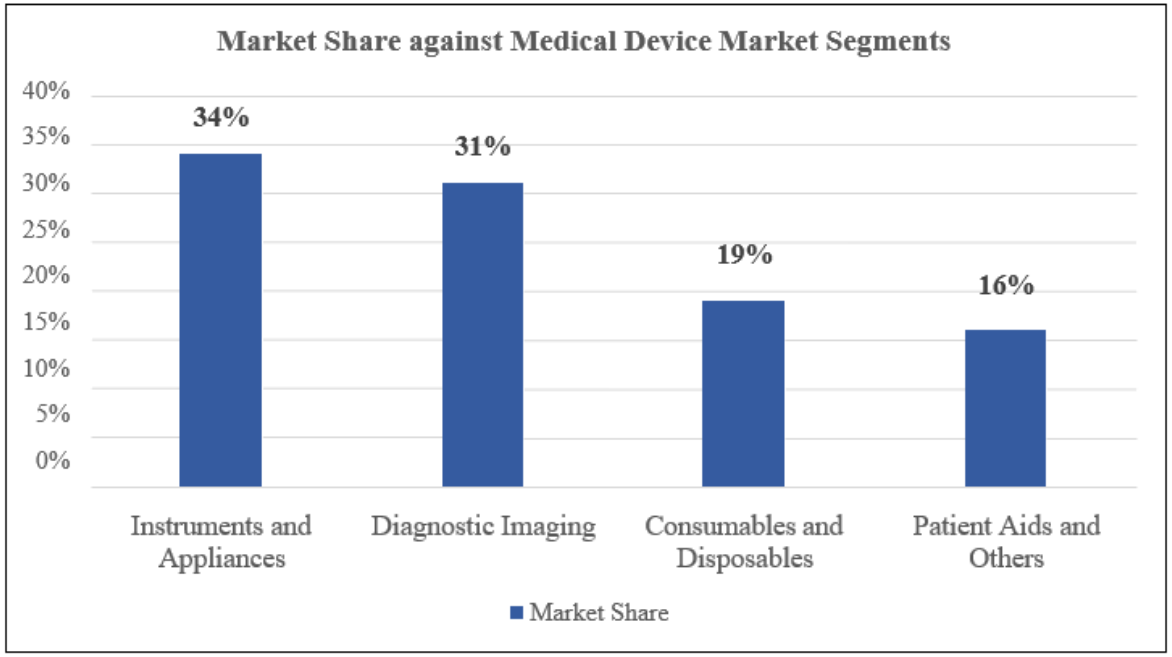
- PTD: Price-to-Distributor (price at which manufacturers sell to distributors)
- TM: Trade Margin
- GST: General Sales Tax

Overview of Medical Devices Industry in India:

- India is home to the top 20 medical device industries globally.
- The market for medical devices in India was valued at $10.36 billion in 2020 and is projected to grow at a CAGR of 37% to reach $50 billion by 2025.
- The industry comprises both small and medium-sized businesses (SMEs) and multinational organizations.
- India has 750-800 domestic medical device manufacturers with an average investment of $2.3-2.7 million and average revenue of $6.2-6.9 million.
- Key suppliers in the Indian market include Phillips, Wipro GE Healthcare, Medtronic, Johnson & Johnson, Becton Dickinson, Abbott, and Hindustan Syringes & Medical Devices.
- Import dependency on medical devices was 75-80% in 2019-20, with imports valued at $5.6 billion. Exports were $2.51 billion in the same period and expected to reach $10 billion by 2025.
- Haryana, Telangana, Karnataka, Gujarat, and Tamil Nadu serve as manufacturing hubs for medical devices in India.
- The major export destinations for Indian medical devices are the US, China, Brazil, France, Germany, and Iran.



- **Market Segments In India :**
  - Consumables and Disposables: Includes stents, syringes, needles, catheters, suturing supplies, bandages, and dressings.
  - Diagnostic Imaging: Involves equipment for radiation, electrodiagnostic testing, and imaging parts and accessories.
  - Tools and Supplies: Covers surgical and non-surgical equipment, as well as other tools and supplies.
  - Patient Aids and Other Items: Encompasses pacemakers, prosthetics and orthotics, and hearing aids.
- **Indian Government Initiatives:**
  - 2017 Medical Devices Rules (MDR): Regulates clinical research, production, importation, sales, and distribution of medical devices.
  - Production Linked Incentive Schemes: Introduced to boost domestic production in target categories and in-vitro diagnostics.
  - Establishment of Medical Device Parks: Approved to provide shared infrastructural facilities, foster a manufacturing ecosystem, and reduce costs.
  - Foreign Direct Investment (FDI): 100% FDI permitted through automatic route for both brownfield and greenfield investments.



Impact of COVID-19 on the Medical Devices Industry in India:

Challenges faced during the pandemic

- Negative financial impact
- Supply chain disruptions
- Operational challenges
- Crisis response strategies

Opportunities and positive outcomes

- Adoption of medical devices in smaller healthcare facilities
- Increased demand for at-home medical equipment
- Growth of new companies in the medical devices sector
- Increase in production capacity of essential medical devices (PPE kits, ventilators, masks, etc.)

Type of equipment's	Medical Device name
Personal protective equipment	Respirators
	Surgical Masks (2-ply; 3-ply; N-95 masks etc.)
	Face shield
	Gloves
	Protective goggles
	Surgical gowns
Medical Equipment	Digital thermometer
	Pulse oximeter
	Glucometer
	Nebulizer
	Oxygen Concentrators
	Ventilators
	Blood Pressure Monitoring Device

REVIEW OF LITERATURE

Balarajan, Y., Selvaraj, S., & Subramanian, S. (2011). *Health care and equity in India*. The Lancet, 377(9764), 505–515

Section 1: Summary of the Literature

- Balarajan, Y., Selvaraj, and Subramanian, S. (2011) conducted a study on health care and equity in India.
- The study revealed that healthcare costs push more than half of Indian households into poverty, with over 39 million Indians becoming impoverished each year.
- High out-of-pocket medical expenses disproportionately affect private families and represent more than one-third of total healthcare spending in India.
- The study identified main obstacles to equity in finance, service delivery, and reducing financial risk in India, including uneven resource distribution, shortage of health-related human resources, access barriers to high-quality healthcare, high out-of-pocket costs, healthcare spending inflation, and behavioral factors influencing demand for appropriate care.

Section 2: Findings from the Literature

- Only a little over 10% of Indians have any type of social or voluntary health insurance.
- Out-of-pocket spending on health has risen over time as a percentage of household spending in both rural and urban areas.
- Drug costs constitute a larger portion of out-of-pocket expenses for the poor compared to the non-poor, and drug expenditures have been increasing.
- Inadequacies in drug price management, pharmaceutical market regulation, and procurement and distribution processes contribute to unequal access to reasonably priced, high-quality medications.

Soni, P., & Gupta, S. (2015). Need for New Pharmacoeconomics Policy for Regulating Prices of Medical Devices In India. Value in Health, 18(7), A573.

Section 1: Summary of the Literature

- Soni, P., & Gupta, S. (2015) highlighted the need for a new pharmacoeconomics policy to regulate prices of medical devices in India.
- The study emphasized two main reasons for price regulation: overdependency on imported products and overpricing of medical devices to patients.
- The Indian medical equipment market relies heavily on imports, particularly for disposables, consumables, surgical instruments, medical electronics, hospital equipment, implants, and diagnostics.
- Multinational corporations control a significant portion of the market without manufacturing facilities in India.

Section 2: Findings from the Literature

- The study reported that a higher reliance on imported goods and a lack of price controls in India resulted in overcharging patients by doctors, hospitals, and retailers for certain medical devices.
- Examples included the Abbott Drug Eluting Stent (DES) imported for $640 and sold for $2000, with a markup of over 250%, and the Medtronics stent imported for $485 and sold for $2600, with a markup of over 200%.
- Overpricing of medical devices poses a significant financial burden on patients and highlights the necessity for price regulations in the industry.

Wadhera, P., Alexander, T., & Nallamothu, B. K. (2017). India and the Coronary Stent Market. Circulation, 135(20), 1879–1881.

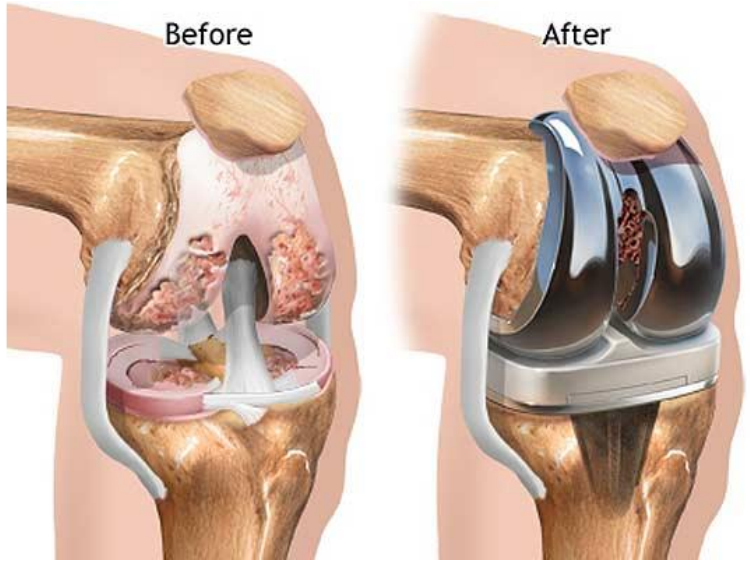
Section 1: Summary of the Literature

- Wadhera, P., Alexander, T., & Nallamothu, B. K. (2017) explored the impact of price ceilings on Indian patients and the local coronary stent market.
- The study focused on the policy change of price capping on coronary stents in India, which aimed to address the treatment of cardiovascular diseases in a country with a rising burden of non-communicable diseases.
- The price cap on stents was expected to improve pricing and increase access for Indian patients.

Section 2: Findings from the Literature

- The report highlighted the potential impact on the market supply as a result of the price ceiling on coronary stents.
- With international manufacturers responding to the drastic price decrease by leaving the market, the new price regulations created an opportunity for local stent makers to gain a larger market share.
- The long-term implications of the price capping policy on the Indian coronary stent market, including its effects on patient access and local industry dynamics, remain to be seen.

Sanghavi S. (2018). CORR International-Asia Pacific: Is Price Capping of Knee Replacement Implants in India a Good Idea?. Clinical orthopaedics and related research, 476(3), 469–472.



Section 1: Summary of the Literature

- The article titled "CORR International-Asia Pacific: Is Price Capping of Knee Replacement Implants in India a Good Idea?" discussed the government's decision to implement price capping on knee replacement implants.
- The National Pharmaceutical Pricing Authority (NPPA) set a price cap on total knee replacement implants, reducing their cost by 59% to 69%.
- The price capping aimed to prevent overcharging by manufacturers, suppliers, and hospitals, alleviating the financial burden on patients.
- The NPPA found that suppliers had significant profit margins, averaging 313% for main knee implants and 369% for revision knee implants

Section 2: Findings from the Literature

- The price capping resulted in a significant reduction in the average maximum retail price (MRP) for knee implants, ranging from -65% to -69%.
- The price capping allowed for a profit margin of 40% for cobalt chromium implants and 30% for titanium, high-flexion, oxidised zirconium, and other materials.
- The article also highlighted some shortcomings of the price capping policy, including the potential for hospitals to increase incidental charges or peripheral costs to compensate for the price deficit.
- There is a risk that manufacturers may consider withdrawing their implants from the Indian market if the ceiling prices are not viable for their business.
- Additionally, the price capping does not include the costs of instruments or additional components used during knee replacement surgery.

Anon. (2022). Introducing more transparency in India's medical device price regulation methods. Ikigai Law.

Section 1: Summary of the Literature

- The article discusses the need for more transparency in India's medical device price regulation methods.
- It explains the concept of Trade Margin Rationalisation (TMR) and its role in controlling medical device costs.
- The article highlights the complex supply chain involved in the medical device industry and the various expenses incurred along the supply chain, which ultimately impact the device prices.
- The study emphasizes the importance of considering factors such as raw material costs, resource costs, value adding costs, compliance, and other costs when regulating medical device prices

Section 2: Findings from the Literature

- Trade margin is defined as the difference between the price to patients (maximum retail price) and the price at which manufacturers sell the devices to distributors (price to trade).
- The National Pharmaceutical Pricing Authority (NPPA) uses TMR to calculate the maximum retail price of medical equipment.
- The article presents the formula used by the Pricing Authority to determine the maximum retail price based on trade margin and other factors.
- The NPPA implemented price controls on certain medical devices, including pulse oximeters, blood pressure monitoring machines, nebulizers, digital thermometers, and glucometers, using the TMR approach.
- Different stakeholders in the medical device sector have varying opinions on where to establish the point of first sale for pricing control.
- Some suggest using the landing price or the point of first sale for importers, while others argue for ex-factory pricing for domestically produced devices.
- Importers emphasize considering trade margin from the moment of first sale to account for additional costs such as training, product liability, and technical support.

NEED FOR THE STUDY, STUDY OBJECTIVES, AND RESEARCH METHODOLOGY

Need Of The Study;

- In 2020, the Indian government classified medical devices as 'drugs' and subjected them to price control regulations, similar to pharmaceuticals.
- The implementation of price regulation aims to prevent excessive profits and improve access to affordable healthcare, but it can affect the profitability of companies and lead to the exit of some firms from the market.
- This study aims to assess the extent and transparency of price control regulations on medical devices in India and evaluate their impact on manufacturers and importers in the country.

Objectives of the Study

Primary Objective of the study is to perform An evaluation of Indian medical device industry's exposure to price control regulation.

Secondary Objective

- The study aims to determine the extent of price control regulation and its transparency in the medical device sector in India.
- It seeks to assess the variability in prices between different brands of the same medical devices and examine how price control regulations impact this interbrand price variability.
- The study aims to evaluate the overall impact of price control regulations on the prices of medical devices, as well as their specific impact on individual brands and companies.

Research Methodology:

- Exploratory research was conducted using secondary data.
- Data sources included office memorandums, working sheets, Gazette Notifications, research articles, and news articles.
- Official websites of NPPA, CDSCO, and DPCO 2013 were searched for pricing data.
- Medical devices were selected based on price control criteria and availability of price and usage data.

Key Methodology Steps:

1. Determine the extent of price control regulation and transparency.
2. Assess interbrand price variability between different brands of the same medical devices.
3. Evaluate the impact of price control regulations on overall medical device prices, individual brands, and companies.
4. Compare the impact of price control regulations on domestic and international medical device companies.
5. Compare changes in price and usage of medical devices.

Calculations:

- Percentage price reduction before TMR: (Old MRP - Revised MRP) / Old MRP * 100
- Interbrand price variability: (Highest Priced Brand - Lowest Priced Brand) / Lowest Priced Brand * 100
- Percentage price reduction with respect to PTR (for price capping): (PTR - Average PTR) / PTR * 100

Medical Devices Included:

- Pulse Oximeter, Nebulizer, Blood Pressure Monitoring Device, Digital Thermometer, Glucometer, Oxygen Concentrator, Condom, Hormonal IUD, IUD Containing Copper, Drug Eluting Stent, Cardiac Stent, Orthopaedic Knee Implant.

DATA ANALYSIS

AND INTERPRETATION

Transparency in Price Control on Medical Devices in India:

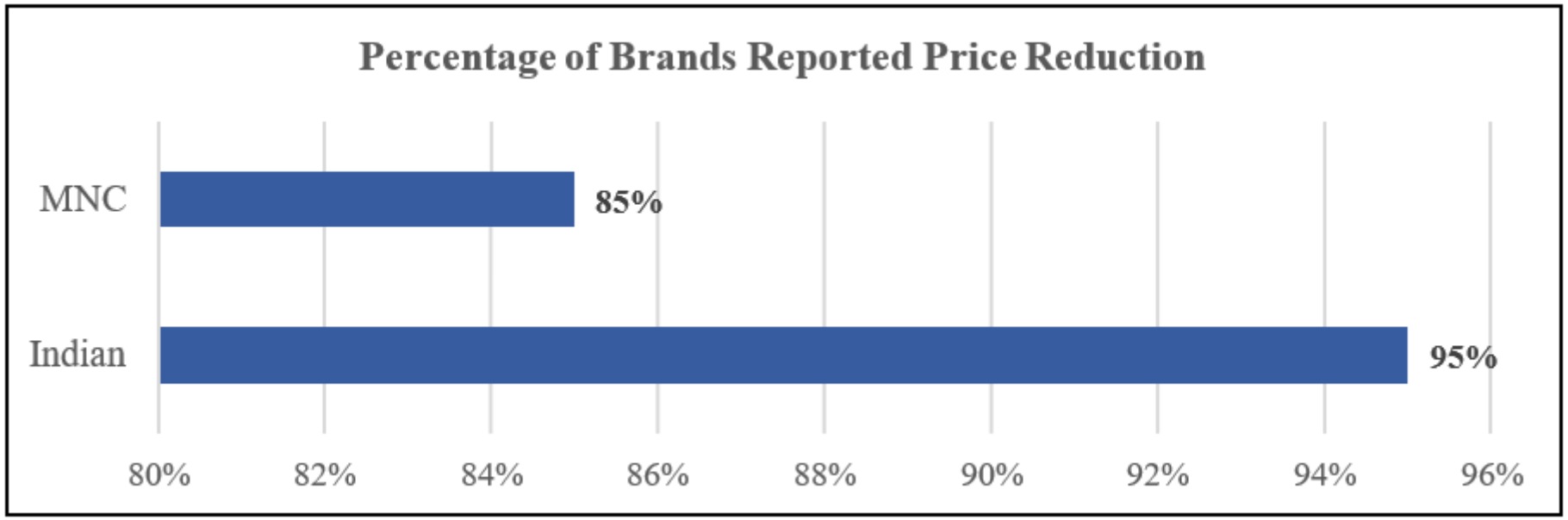
The research conducted on transparency in price control on medical devices in India revealed a lack of sufficient data and transparency regarding the pricing calculations used by the National Pharmaceutical Pricing Authority (NPPA) and other official sources. The study focused on evaluating the availability of different sets of pricing data used by the NPPA for determining the ceiling price and trade margin for medical devices.

In comparison to drug formulations, the research found that there was insufficient data provided by the NPPA or any other official source regarding the pricing data

Comparison between Indian and Multinational Companies

There were total 105 companies (81 Indian and 24 MNCs) notified under TMR. For both Indian companies and MNCs, the prices were reduced by 40-60% for majority of their brands. However, there were more number of MNC brands reporting a price reduction in the range of 80-100%.

S.No.	Company Type	Number of Companies	Number of Brands Reported Price Reduction	Number of Brands by Percentage Price Reduction				
				0-20 %	20-40 %	40-60 %	60-80 %	80-100 %
1	Indian	81	697 (735)	141	211	247	95	3
2	MNC	24	199 (234)	37	44	84	24	10


Percentage of Brands Reported Price Reduction
MNC
85%
Indian
95%
80%
82%
84%
86%
88%
90%
92%
94%
96%

SUMMARY OF FINDINGS AND RECOMMENDATONS

SUMMARY OF FINDINGS

1. Among the 347 medical devices listed by CDSCO in India, only 12 (3.45%) were under some form of price control implemented by NPPA.
2. NPPA employed two approaches for price control: Price Capping and Trade Margin Rationalisation (TMR). TMR applied to six devices, while price capping applied to the remaining six.

Lack of transparency and data availability regarding pricing was observed, with NPPA not providing price calculations or data sources for seven out of twelve devices under price control, highlighting a need for improved transparency

RECOMMENDATONS

- To ensure better affordability and access to essential medical devices, the government should expand the scope of price control to a wider range of devices that are high in demand and crucial for diagnosing, preventing, monitoring, treating, or managing serious diseases or disorders.
- The price control measures should consider the overall cost of the procedure, including accessories and equipment, rather than solely focusing on the cost of the medical device. This would prevent gaps in price capping and mitigate the increased overall procedure cost despite price control.
- NPPA should enhance transparency by providing verifiable data sources and releasing detailed price calculation sheets, similar to the approach used for drug formulations, to ensure transparency and facilitate informed decision-making in pricing policies for medical devices. Additionally, a reassessment of the pricing policy and its implementation is necessary to address the lack of impact on interbrand price variability.


thank you