



**Dr. Ranjeet Mehta**  
CEO & Secretary General

Ind-54-health-  
7<sup>th</sup> February 2025

*Hon'ble Chief Minister,*

**Subject: Request for Reconsideration of Pricing for Cardiac Stent Implant Package under RSHAA**

PHD Chamber of Commerce and Industry (PHDCCI) has been working as a catalyst for the promotion of Indian industry, trade and entrepreneurship for the past 120 years. It is a forward-looking, proactive and dynamic PAN-India apex organization. As a partner in progress with industry and government, PHDCCI works at the grassroots level with strong national and international linkages for propelling progress, harmony and integrated development of the Indian economy.

PHDCCI, acting as the "Voice of Industry and Trade" reaching out to more than 1, 50,000 large, medium and small industries, has forged ahead leveraging its legacy with industry knowledge across multiple sectors to take the Indian economy to the next level.

At the global level, we have been working with the Embassies and High Commissions in India and overseas to bring in the International best practices and business opportunities.

Firstly, we would like to express our sincere appreciation for the commendable efforts of the Rajasthan State Government and your esteemed office in strengthening healthcare accessibility and affordability in the state. The proactive measures taken under your leadership to enhance public health services and ensure quality medical treatment for the people of Rajasthan are truly commendable. The emphasis on structured procurement policies and evidence-based decision-making reflects a strong commitment to patient welfare and sustainability in the healthcare sector.

It is in this spirit of constructive engagement that we wish to bring to your kind attention certain concerns arising from the **recent notification F.7 (08) RSHAA/Medical/Coronary Stent/ 286 (A) dated 27th January 2025 by the Rajasthan State Health Assurance Agency (RSHAA) regarding the reimbursement pricing of Drug Eluting cardiac stents packages**. The decision to set the reimbursement at ₹23,625 only for companies that have conducted randomized clinical trials (RCTs) on 2,000 patients with three-year follow-up data, while capping the price for all others at ₹12,500, creates significant challenges for new-generation technologies and emerging domestic manufacturers.

**Key Concerns & Violation of Public Procurement Policies:**

**1. Violation of Fair & Equitable Treatment Principle (2012 Act, Section 4)**

The Rajasthan Transparency in Public Procurement Act, 2012, mandates **fair competition and equitable treatment of bidders**. However, the criteria set forth in the notification:

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- **Creates a biased advantage for older manufacturers** who have been in the market longer and possess clinical data generated on their older generation products.
- **Excludes and discriminates against newer generation manufacturers directly on the basis of pricing**, thereby restricting fair competition.
- **Contradicts procurement principles** by artificially limiting participation and creating monopolistic market conditions.

## 2. Discriminatory Procurement Criteria & Restriction of Competition

- The requirement of a **2,000-patient RCT with three-year follow-up data arbitrarily disadvantages new manufacturers**, despite no scientific evidence that older stents with longer trials are superior.
- The **National Pharmaceutical Pricing Authority (NPPA)** and **Central Drugs Standard Control Organization (CDSCO)** do not mandate any such trial requirements for pricing fixation and regulatory licensing.
- This restriction goes against **Section 6(1) of the Act**, which prohibits the establishment of procurement conditions that discriminate against any category of bidders.

3. **Absence of Such Discriminatory Criteria at the Central Government Level:** At the national level, reimbursement pricing for cardiac stents under schemes like CGHS and Ayushman Bharat does not enforce such restrictive parameters. The National Pharmaceutical Pricing Authority (NPPA) and the Central Drugs Standard Control Organization (CDSCO) follow globally accepted regulatory pathways to ensure quality and efficacy without favoring select manufacturers. The Rajasthan State Health Assurance Agency's new criteria, however, create an artificial barrier that benefits only a handful of companies, contradicting the central government's inclusive and fair approach.

**Moreover, Drug Eluting Stent is a generic product as it has been in the market since more than 23 years and is a combination of metal implant and generic unpatented drugs like Sirolimus or Everolimus which are freely available worldwide to be used on Stents.**

4. **Selection Parameters Favoring Older Technologies Over Innovation:** The requirement of a 2,000-patient RCT with three-year follow-up data inadvertently favors older-generation stents of some companies, such as stainless-steel variants, which have been in the market for decades **but are not MRI safe**. The latest generation of stents, incorporating biocompatible polymers and optimized drug-eluting formulations, are clinically proven to be safe and effective through global and domestic regulatory approvals. However, they may not yet have the specific long-term data required by this notification, putting them at an unjust disadvantage.
5. **Lack proven safety & efficacy of RCT in Indian Patients:** Moreover, the notification **doesn't mandate the requirement of the Clinical Trial on Indian Patients**. While lot of domestic companies are generating robust set of clinical data specifically on Indian patients through various clinical registries conducted in India would be at huge disadvantage because of the parameters cited in the notification.

- **Impact on Future Research and Innovation:** The introduction of this restrictive criterion sends a signal that newer, advanced-generation stents are inferior, which is misleading and detrimental to future research and development. The cardiac stent industry thrives on continuous innovation, where new materials, coatings, and manufacturing techniques significantly enhance patient outcomes. **Enforcing such rigid requirements discourages investment in research, potentially slowing down the adoption of next-generation technologies in Rajasthan.**

#### **6. Lack of Broad Consultation & Transparency in Decision-Making**

- The pricing decision was made by a committee consisting only of doctors from one Hospital.
- The **Rajasthan Transparency in Public Procurement Act, 2012**, mandates **broad stakeholder consultation**, including:
  - **Industry representatives** (domestic manufacturers).
  - **Independent researchers.**
  - **Medical experts from multiple institutions.**
- The absence of such diverse consultation **raises concerns over transparency and fairness** in this decision-making process.

#### **Our Request:**

In light of the above concerns, we urge the Rajasthan State Government to reconsider this notification and adopt a more inclusive approach that fosters fair competition, promotes innovation, and ensures the best clinical outcomes for patients. we respectfully urge the Rajasthan State Government to:

1. **Reconsider this notification** and ensure that new domestic manufacturers receive fair market access.
2. **Mandate a uniform pricing structure for all cardiac stents exclusively approved by the National Regulatory Authority of India (CDSCO), eliminating any prerequisite for USFDA or CE certification, additional clinical trials, or discriminatory differentiation, ensuring an equitable and non-biased regulatory & pricing framework.**
3. **Align the reimbursement policy with the central government's approach**, which does not enforce restrictive parameters favoring a select few manufacturers.
4. **Mandate broader stakeholder consultation**, ensuring that Rajasthan-based manufacturers and industry experts are included in pricing decisions.
5. **Ensure compliance with Fair & Equitable Treatment Principle (2012 Act, Section 4)**

Mr. Jatin Nagpal, Joint Secretary, PHDCCI at 98995 85780 or jatin.nagpal@phdcci.in, or Ms. Aditi Bhardwaj, Deputy Secretary, PHDCCI at 7982187735 or aditi.bhardwaj@phdcci.in will get in touch with your office for any further coordination.

We look forward to your kind confirmation and support in this regard.

With best regards,

Yours sincerely,



(Dr. Ranjeet Mehta)

**Shri BhajanLal Sharma,**  
Hon'ble Chief Minister,  
Rajasthan

**CC: Smt. Gayatri A. Rathore,**  
Principal Secretary To Government,  
Medical & Health And Family Welfare  
And Panchayati Raj (Medical And Health) Department,  
Rajasthan, Jaipur

**Smt Priyanka Goswami,**  
CEO,  
State Health Assurance Agency,  
Jaipur

**Attachment:**

- Notification F.7 (08) RSHAA/Medical/Coronary Stent/ 286 (A) dated 27<sup>th</sup> January by RSHAA