Press Release on 164th Report of the Committee on Petitions, Rajya Sabha on the Petition praying to evolve an efficient mechanism to check the exorbitant prices of cardiac stents and other medical devices

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The Committee on Petitions, Rajya Sabha, headed by Shri Narain Dass Gupta, M.P. presented its 164th Report on a Petition submitted by Ms. Sulagna Chattopadhyay, r/o Vasant Kunj, New Delhi and countersigned by Shri Avinash Rai Khanna, the then Member of Rajya Sabha, "*praying to evolve an efficient mechanism to check the exorbitant prices of cardiac stents and other medical devices in the country*". The petition was admitted by Hon'ble Chairman, Rajya Sabha on 20th October, 2015 under the provisions of Chapter X of the Rules of Procedure and Conduct of Business in Council of States (Rajya Sabha). In accordance with Rule 145, the petition was reported to the Council on 2nd December, 2015 by Shri Avinash Rai Khanna, after which it was referred to the Committee on Petitions for examination and to report in terms of Rule 150.

The Committee deliberated upon this petition at length during its six meetings held from December, 2015 to March, 2017 and heard various stakeholders including the petitioner, Secretaries, Ministry of Health & Family Welfare and Department of Pharmaceuticals along with the Chairman, National Pharmaceutical Pricing Authority (NPPA) on the modalities of fixation of price of cardiac stents. As the petition raised the issue with specific reference to cardiac stents, the Committee decided to first take up the issue of exorbitant prices of cardiac stents. The Committee also decided to present the Report on the petition in two parts; first, a Report on the exercise done on reducing the prices of cardiac stents and second, a comprehensive Report covering the entire gamut of the petition. Accordingly, the Committee considered and presented the same to the Rajya Sabha on the 6th April, 2017, urging upon the Government to inter alia bring down the prices of cardiac stents. Pursuant to the recommendations of the Committee, the Government put the mechanisms in place to bring down the prices of the stents resulting in sharp reduction in their ceiling prices. The **Action Taken Report (ATR) received** from the concerned Ministry was considered, found satisfactory and closed by the Committee in its meeting held on the 18th February, 2019. The Committee thereafter took up further examination of the petition in the year 2021.

4. The Committee during the course of further examination of the petition, focused on the other medical devices. The Committee held discussions with the Secretaries of Ministry of Health & Family Welfare and Department of Pharmaceuticals along with the Chairman, NPPA, Drug Controller General of India (DCGI) as well as the representatives of Confederation of Indian Industries (CII), Associated Chambers of Commerce & Industry of India (ASSOCHAM) and Federation of Indian Chambers of Commerce & Industry (FICCI). Further, the Committee also held interactions with the representatives of prominent hospitals, manufacturers of medical devices and other stakeholders across the country along with Officers of the Ministry of Health & Family

Welfare and Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers during its study visits.

The report of the Committee is available on the Rajya Sabha Website https://sansad.in/rs/committees/8?standing-committees.

The Recommendations/Observations of the Committee have been annexed for reference.

RECOMMENDATIONS OF THE COMMITTEE-AT A GLANCE

1. The Committee notes that clubbing medical devices and pharmaceuticals under same rules poses unique challenges like price controls intended for medicines, causing unintended economic, reduced profit margins, and, in some cases, the withdrawal of high-end devices from the market. The Medical Device Rules often fail to address high-end, complex medical equipment maintenance and software, forcing them into a framework designed for pharmaceuticals. The Committee observes that this scenario discourages production and investment in the sector. Therefore, the Committee recommends that the Government should consider providing distinct categorisation of drugs and medical devices and likewise distinct rules for the same.

(Para 3.5)

2. The Committee observes that patients should be the centre of healthcare policies and any policy framed by the Government that is contrary to their interests will be detrimental to the development and well being of the society. The hospitals and health providers are intermediaries. The Government should launch consumer awareness programmes to educate the patients about the various medical devices and the information regarding the pricing and availability of the devices should be prominently displayed.

(Para 3.5.1)

3. The Central Drugs Standard Control Organisation (CDSCO) should play a decisive role in propelling the manufacturing and innovation in the medical devices sector by simplifying the licensing regime. Timelines for issuing of licences should be revised as it has been reported that delaying tactics are adopted causing undue harassment to the applicants. A simplified licensing system will encourage foreign investment and technology which is crucial for the economy and for the sector.

(Para 3.5.2)

4. The Committee notes the submission regarding exhaustive clinical trials causing cost escalations. The Committee recommends that the guidelines regarding clinical trials may be reviewed, aiming to lower the financial barrier to encourage small manufacturers while ensuring that patient safety is not compromised.

(Para 3.5.3)

5. The Committee expresses concern at the fact that the consumers do not receive any benefit of the recoveries made from the manufacturers on account of overcharging. The intention was to make a law so that the benefit is passed on to the consumer and the price sensitivity remains for the consumer. However, the consumer does not receive any reimbursement for the overcharged costs. Therefore a strong monitoring mechanism is required to prevent any overcharging. The overcharged amount going back to the treasury is not the solution because ultimately the consumer should get the benefit. The Committee recommends that it is an area that needs to be looked into. The penalties need to be heavy and the regulations need to be effectively implemented.

(Para 4.5)

6. The Committee is concerned at the contention that the Department of Pharmaceuticals does not have any role in the pricing of diagnostic, scanning and imaging services. It is concerning to note this fact as the Ministry of Health & Family Welfare also states that pricing is not under their domain. The Committee strongly recommends that the concerned Ministries, i.e. Health & Family Welfare, Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers should work in coordination to come up with a uniform policy on pricing of diagnostic services so that the patients are not disadvantaged, as the cost of diagnostic procedures substantially add to the treatment costs. Already faced with exorbitant cost of treatment, disparities regarding the pricing among the authorities do not bore well on the well being of the end users. The plethora of regulations does not serve any purpose if the end consumer continues to bear the exorbitant cost of treatment coupled with high out-of-pocket-expenses. It has been widely reported that patients across the country have to bear significantly high out-of-pocket-expenses, which clearly displays that the number of regulations framed by the Government does not percolate to the consumer, defeating the objective of welfare which is central to the policy framework.

(Para 4.5.1)

7. The Committee notes with concern the difference between MRP and actual production cost of electronic devices and agreed with the stakeholders that more and more localization/indigenisation is the way forward to control and reduce prices of medical devices and dependence on imports to compete with low cost imported products.

(Para 4.9.2)

8. The Committee appreciates the significant achievement of NPPA in reducing prices of cardiac stents by up to 85% and knee implants by up to 70%, resulting in annual savings of approximately ₹ 5,900 crore to the public. However, the Committee is deeply concerned that despite the price ceiling, the total procedure cost remains high due to unregulated procedural charges, which constitutes 60-70% of total treatment costs. Therefore, the regulatory mechanism to control the unregulated procedural charges should be strengthened.

(Para 4.10.1)

9. The Committee notes with concern the views of SKIMS that AB-PMJAY coverage for cardiac catheterization has been reduced from 100% to 50%, leaving patients to bear substantial out-of-pocket expenses. The Committee strongly recommends that the Government review and enhance insurance package coverage under AB-PMJAY to match the actual costs of procedures, particularly for cardiac catheterization, cardiac surgery, neurosurgery, and interventional radiology. The package rates should be revised regularly based on ground reality rather than outdated estimates.

(Para 4.10.2)

10. The Committee noted with concern, that patients have to purchase premium neurosurgical items like aneurysm clips, PEEK (polyetheretherketone) **cages, and 3D mesh, as they are unavailable through subsidized Government channels. Similarly, patients have to bear 40% of valve costs and 70% of aortic stent costs in cardiac surgery, which is a significant expenditure. The Committee strongly recommends that the Government urgently expand the list of price-regulated medical devices to include:**

(i) Prosthetic heart valves (mechanical and bio-prosthetic)

(ii) Pacemakers (single-chamber, dual-chamber, CRT)

(iii) Neurosurgical implants (aneurysm clips, PEEK cages, 3D mesh)

(iv) Advanced stents (aortic stents, flow diverters, neurocoiling devices)

(v) Other Class C and Class D life-saving devices currently unregulated

(Para 4.10.3)

11. The Committee endorses the recommendation of Sri Jayadeva Institute of Cardiology, Bengaluru, that devices such as rings, mechanical valves, and pacemakers should be brought under price control to ensure affordability for cardiac patients.

(Para 4.10.4)

12. The Committee notes the concerns raised by AIMED regarding the artificially inflated MRP system where hospitals preferentially consume high-MRP goods over low-cost options, driven by profit motives rather than patient affordability. The Committee recommends that:

(i) NPPA should monitor MRP of imported medical devices and compare with import landed prices, taking action when margins are found to be irrationally excessive.

(ii) A pilot study should be undertaken on test cases to cap MRP over imported landed price or ex-factory price (first point of sale when goods enter supply chain).

(iii) Hospitals should be mandated to offer patients a choice between different brands at different price points, displaying comparative prices prominently.

(iv) Trade margin restrictions should be applied equitably to both domestic and imported products to prevent competitive advantage to overseas brands.

(Para 4.10.5)

13. The Committee is concerned about the MRP-production cost gap highlighted by the stakeholders. The Committee recommends that the Government commission a comprehensive study on pricing structures of medical devices, including component costs, manufacturing costs, distribution margins, and retail mark-ups, to identify and curb profiteering at each stage of the supply chain.

(Para 4.10.6)

14. The Committee recommends that the Jan Aushadhi Kendras and AMRIT Pharmacy networks should be expanded significantly to cover all districts, with a special focus on rural and underserved areas. The range of medical devices offered through these channels should be expanded beyond the current 121 devices in 277 variants to include more high-value implants and life-saving devices.

(Para 4.10.7)

15. The Committee notes with concern, the response of the Ministry on a crucial aspect related to the pricing of medical devices. The success of a Government scheme or policy is dependent on its outcomes. Without assessing the outcomes, the objective of the scheme is lost. The PLI Scheme does not have a direct bearing on the price of medical devices. However, the intention of the scheme is to enhance domestic production of medical devices, which will subsequently lead to availability of medical devices at reasonable rates to the consumers. During a discussion, the Committee was informed that a Study to assess the benefits to the consumers would be conducted but the Committee notes with concern that the Ministry has not conducted the study. Therefore, the Committee recommends that the Ministry should conduct a study to assess the benefits accrued to the consumers due to the implementation of the Production Linked Scheme, which should also include the pricing of diagnostic services. Besides, the Committee recommends that the Government should also conduct a study to assess the difference between the landed cost and the maximum retail price of imported medical devices to get clarity on the pricing.

(Para 5.5)

16. From the data furnished by the Ministry the Committee has observed that only major players are participating in the PLI Scheme. The Committee recommends that MSME sector should also receive the benefits of the scheme and the required financial assistance so that they are also able to contribute in the strengthening of medical devices sector in the country and generate employment.

(Para 5.5)

17. The Committee commends the AMRIT Pharmacy initiative by HLL Lifecare Ltd., which provides medical devices and medicines at 15% less than average market prices with only 5% margin. With 207 AMRIT stores currently operational in public sector hospitals, the Committee strongly recommends nationwide expansion of this model to all Central Government hospitals, AIIMS, and major State Government hospitals across all states and union territories on a time bound basis.

(Para 5.7.1)

18. The Committee appreciates the patient-centric model of Sri Jayadeva Institute of Cardiology, Bengaluru, where procedure costs are fixed at actual cost without any margin, resulting in 30-40% less cost than the private hospitals while serving 70-80% patients from poor and needy sections. The Committee recommends that this zero-margin model for medical devices and procedures should be adopted as a standard practice in all Government hospitals and medical colleges across the country.

(Para 5.7.2)

19. The Committee notes with concern that the projects for developing Mediparks have been lying idle for years despite the sanction by the Central Government, and most of them are not functional. As per the data furnished by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers only three states have been allocated MedTech Parks, whereas, it should have been ensured that these are spread across the country in an even manner. The Committee strongly recommends that the Central Government should urgently intervene to expedite negotiations with the concerned State Governments to operationalize these Mediparks at the earliest, developing it as a medical cluster and knowledge park with manufacturing facilities.

(Para 5.7.3)

20. The Committee commends the Andhra Pradesh MedTech Zone (AMTZ) model, which was built in a record 342 days and now hosts over 100 companies working on medical device R&D and production. During the pandemic, AMTZ demonstrated indigenous capability by producing over 100 ventilators, 500 oxygen concentrators, and 1 million RT-PCR kits daily. The Committee recommends that the AMTZ model should be replicated in at least 10 more states, prioritizing states with existing pharmaceutical/biotechnology ecosystems such as Maharashtra, Gujarat, Karnataka, Telangana, West Bengal, Punjab, Uttarakhand, Madhya Pradesh, and Kerala.

(Para 5.7.4)

21. The Committee appreciates the multi-pronged procurement strategy adopted by AIIMS Jammu involving rate contracts with multiple vendors, MoUs with HLL Lifecare, PMBJK, Kendriya Bhandar, partnership with HITES for equipment procurement, and GeM utilization for emergency needs. The Committee recommends that this comprehensive procurement model should be documented as best practice and adopted by all AIIMS and major Central Government hospitals to ensure uniform pricing, quality assurance, affordability, and timely supply.

(Para 5.7.5)

22. The Committee commends the transparent tender process adopted by JKMSCL for cardiac cath lab items with strict eligibility criteria, sample approval before financial bid opening, and rate reasonableness checks. The Committee recommends that all State Medical Services Corporations should adopt similar transparency measures in procurement, with mandatory technical evaluation before financial bid opening and random rate reasonableness verification to prevent cartelization and ensure genuine competition.

(Para 5.7.6)

23. The Committee notes that India has only five companies producing syringe infusion pumps and they face severe competition from Chinese companies selling at cheaper rates due to export subsidies. This highlights the critical need for policy support to Indian manufacturers. The Committee strongly recommends that the Government should:

(i) Consider raising import duties on many items from the current 5–7.5% range to 10–15% on imported medical devices to provide a level playing field for domestic manufacturers and to protect the "Make-in-India" initiative.

(ii) Provide targeted financial assistance and subsidies to Indian manufacturers competing against subsidized Chinese imports in critical segments.

(iii) Mandate minimum domestic component content requirements in Government procurement, gradually increasing from 40% to 75% over five years.

(Para 6.3.1)

24. The Committee endorses the recommendation for a separate legal framework for medical devices, distinct from drugs, on the lines of FSSAI. The Committee recommends that the proposed Medical Devices Act should decriminalize minor procedural lapses and replace them with a graded penalty system, fostering a compliance-oriented approach rather than a punitive one. This will encourage developers and manufacturers to invest in innovation without fear of criminal prosecution for technical non-compliance.

(Para 6.3.2)

25. The Committee notes that localization and indigenization are the way forward to control prices and reduce import dependency. However, with over 70-80% import dependency, particularly for high-end components, indigenous manufacturing faces significant challenges. The Committee recommends that:

(i) The Government should expand the Production Linked Incentive (PLI) Scheme to cover a broader range of high-end component manufacturing, including sensors, electronic sub-assemblies, specialized materials, and precision parts.

(ii) Medical Device Parks should be equipped with high-cost shared infrastructure such as gamma radiation sterilization plants, advanced testing labs, and prototyping centers to reduce capital expenditure for MSMEs.

(iii) Dedicated Centres of Excellence (CoEs) should be created within Medical Device Parks to train specialized workforce in biomedical engineering, regulatory compliance, and quality management systems.

(Para 6.3.3)

26. The Committee notes that the Export Promotion Council for Medical Devices has been established but needs to be made fully functional. The Committee strongly recommends that the Government should operationalize the EPC-MD immediately with adequate budget allocation and

mandate to:

(i) Assist manufacturers in understanding global regulatory requirements (EU-MDR, US-FDA).

(ii) Organize international trade fairs and buyer-seller meets to promote Brand India.

(iii) Provide market intelligence on export opportunities and competitive positioning.

(iv) Address export barriers such as high logistics costs and inverted duty structures.

(Para 6.3.4)

27. The Committee notes that some of the companies like Morrison's Lifecare are maintaining comprehensive quality systems with physical, chemical, biological, and microbiological testing at various production stages. The Committee recommends that the Government should incentivize adoption of international quality standards (ISO 13485, ISO 13485:2016, IEC 60601) by providing:

(i) Subsidized certification programs for MSMEs.

(ii) Tax benefits for ISO/IEC certified manufacturers.

(iii)Preferential procurement from certified domestic manufacturers in Government tenders.

(Para 6.3.5)

28. The Committee notes with appreciation the indigenous innovation demonstrated by Phoenix Medical Systems in producing vibrating sticks for the visually challenged at approximately ₹5,000, useful for professions like teaching. The Committee recommends that the Government should establish an Innovation Fund specifically for medical devices addressing disabilities and assistive technologies, with grants for each innovation and fast-track regulatory approval for such socially beneficial devices.

(Para 6.3.6)

29. The Committee noted that while foreign approvals (US-FDA or CE) help strengthen a technical dossier, they are no longer a substitute for CDSCO licensing in Indian government tenders as of 2025. This means global innovators face a second, lengthy local approval cycle after already passing rigorous international tests. Hence, in order to achieve the national goal of a $50 billion market by 2030, the Committee propose a Deemed Approval pathway, which will allow devices already certified by globally recognized authorities (e.g., FDA, EU-MDR) to receive an interim Indian marketing license within 30-45 days, provided they meet basic local safety and labelling standards through the National Single Window System.

(Para 6.3.7)

30. The Committee notes that the regulatory framework governing professional conduct of medical practitioners already recognises the risks arising from undue influence of the pharmaceutical and allied health sector industry on clinical decision-making, including choice of drugs, devices and procedures. The Committee observes that clause 6.8 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 explicitly prohibits doctors from accepting gifts, travel facilities, hospitality, cash or monetary grants and from engaging in promotional endorsement of any drug or product, and empowers the Ethics and Medical Registration Board (EMRB) of the National Medical Commission and State Medical Councils to take disciplinary action in case of violations. The Committee is of the considered view that strict and visible enforcement of these

ethical safeguards is critical to ensuring that the choice and use of cardiac stents and other medical devices is driven solely by patient interest and evidence-based medicine, and not by financial or promotional inducements.

(Para 7.1)

31. The Committee recommends that the Ministry of Health and Family Welfare, in coordination with the National Medical Commission and State Medical Councils, should strengthen monitoring and enforcement of clause 6.8 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, particularly in relation to interactions between medical practitioners, hospitals and manufacturers/suppliers of cardiac stents and other high-value medical devices. This should include time-bound disposal of complaints, publication (with due safeguards) of anonymised data on the number and nature of violations and penalties imposed, and periodic circulars/reminders to the medical fraternity reiterating prohibitions on gifts, inducements and product endorsements.

(Para 7.2)

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