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Bridging Indiaâ??s MedTech Gap: From Imports to Innovation

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India must adopt an export-first mindset with regulatory harmonisation

India’s MedTech sector has momentum, but to compete globally we now need depth, predictability, and genuine value addition, not assembly-led growth.

- Regulatory predictability is the industry’s 1st top priority and as recommended by the Parliamentary Committee, India needs a stronger, globally aligned National Medical Devices Regulatory Authority like The Food Safety and Standards Authority of India (FSSAI) which should separate medical devices from drug centric regulatory frameworks and deliver time bound, risk-based approvals based on 3rd party Certification, even for high risk devices, to spur innovation and exports.
- India must build a domestic component ecosystem by policy and tariff incentives — sensors, chips, polymers, reagents, tooling — to end dependence on imports and stop pseudo-manufacturing.
- R&D and IP creation need sustained support through innovation grants, tax incentives, and stronger industry–academia–hospital collaboration and allow overseas technology access commercialisation in these incentives.
- A uniform GST slab - corrected inverted duties with prompt refunds of GST paid on services and CAPEX as per best global practices will address working capital stress due to accumulated GST will help make manufacturing globally competitive, and calibrated import tariffs of minimal 10-15 per cent as for consumer electronics and mobile phones are essential for fair competition.
- MedTech Parks must become fully operational, with shared facilities such as testing labs, sterilisation units, tool rooms, and skilling centres. Each park should be developed as a planned cluster with a clear product technology focus, for example: separate for (1) large, midsized and small consumer medical electronics; (2) stainless steel instruments and orthopedic implants; (3) hospital furniture and equipment; (4) IVD reagents, analyzers and instruments; (5) rubber based consumables and disposables; and (6) plastic based implants etc.
- India must adopt an export-first mindset with regulatory harmonisation, MRAs, and branding support for Indian MedTech.

If these structural reforms are implemented consistently, India can emerge as a globally competitive MedTech manufacturing and innovation powerhouse within this decade.

Bridging the gaps

The industry has responded to recent policy support with renewed confidence and visible investment.

- Companies are expanding domestic manufacturing across imaging, diagnostics, robotics, orthopaedics, renal care, implants and critical-care technologies — a major shift for a country that once imported 80–85 per cent of high-end devices.

- Diagnostics players are moving into AI, molecular testing, automation, and connected health, building integrated digital ecosystems.
- Firms are pursuing US Food and Drug Administration (FDA)/CE (Conformité Européenne) certifications, exports, and global partnerships, signalling ambition to join global supply chains.

But critical gaps persist:

- India still lacks a robust component and raw-material ecosystem, limiting true value addition.
- MSMEs and startups struggle to access capital, incentives, and regulatory pathways.
- The innovation-to-commercialisation gap remains wide due to weak validation and tech-transfer systems.
- Public procurement often blocks market access by insisting on CE/US FDA approvals instead of accepting the Central Drugs Standard Control Organisation (CDSCO) manufacturing licenses or the Quality Council of India (QCI)'s Indian Certification for Medical Devices. The Global Tender exemption list needs to be reviewed and reduced where domestic manufacturing licensed and experienced capacities are available.
- Regulation is improving, but it still needs greater speed, clarity, and harmonisation. Policy reversals, such as reconsidering permissions for pre-owned imports, undercut predictability and investor confidence.
- Balancing affordability with industrial growth remains a policy challenge. Inflated MRPs often pushed through hospital procurement distort the market: patients lack brand choice and bargaining power, while ethically lower priced suppliers are disadvantaged. A separate Fair pricing regulation is needed.

India's momentum is real — but global competitiveness will depend on building the full ecosystem: components, R&D, talent, regulatory capacity, and exports.

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