Highlighting the need for uninterrupted growth in the MedTech industry

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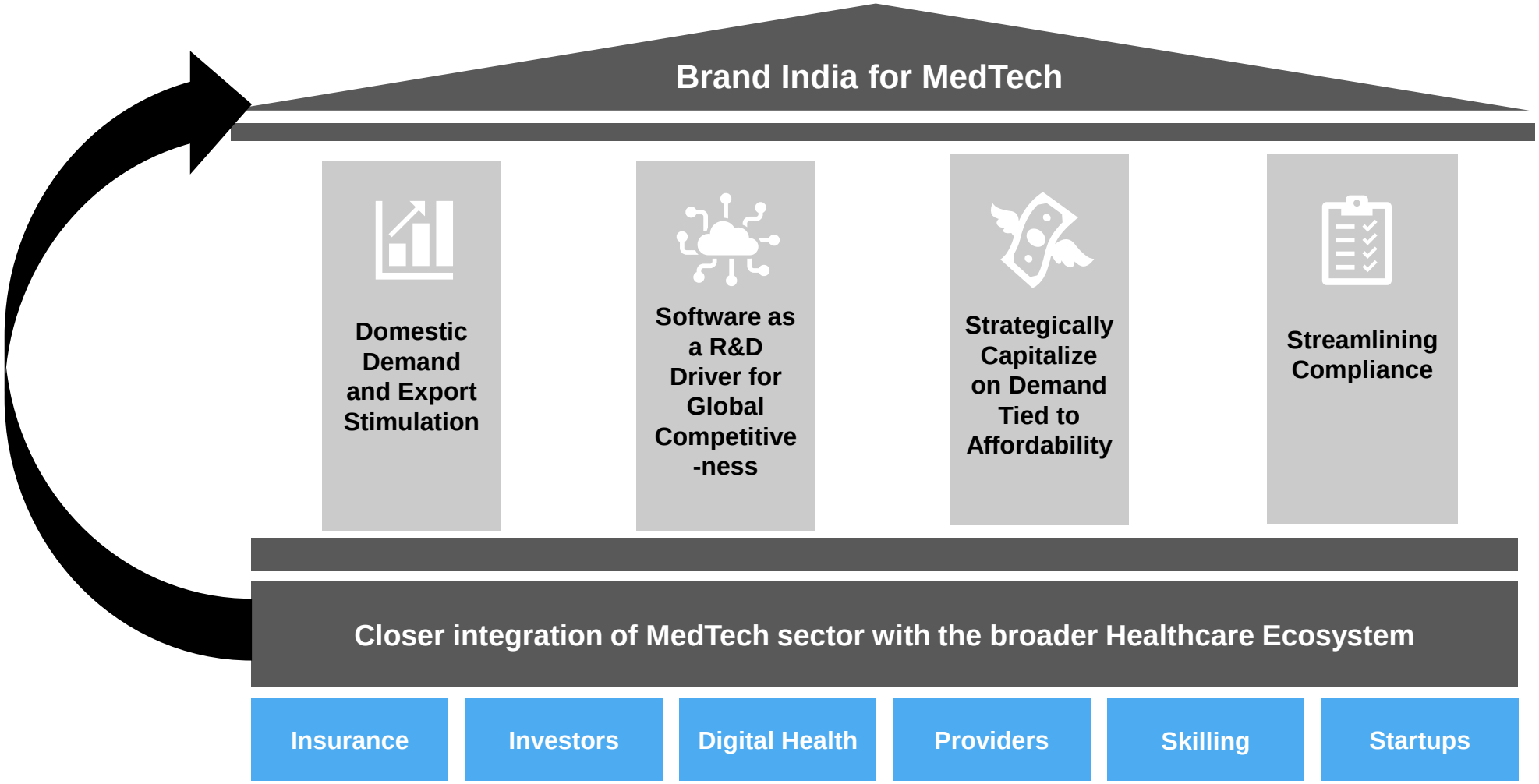
NATHEALTH®
Healthcare Federation of India

Framework for achieving uninterrupted growth in the MedTech industry



1. Domestic Demand and Export Simulation

Comparison of demand ecosystem to more advanced markets

- Per capita MedTech utilization in India (USD 9) vs global average (USD 60)
- Comparison with China (market is 10 years ahead; 2.5x per capita utilization; demand generation factors include insurance, centralized bulk procurement, increasing life expectancy and disposable incomes; surge in demand for advanced imaging devices)

Insurance

- **India:** Insurance generally covers procedures rather than medical devices, focusing on traditional treatments. Since 2018, coverage for advanced procedures like balloon sinuplasty, deep brain stimulation, and robotic surgeries has expanded, boosting demand for related medical devices, though studies quantifying this demand are limited.

Cross-ministerial action

India's medical device procurement model is similar to China's, utilizing GeM (Government e-Marketplace) and state-level tenders, but also includes private sector procurement, creating a mix of centralized and decentralized models.

Case Studies for Implementation Paths:

- China: Centralized bulk procurement (VBP model).
- Japan: Insurance-backed procurement.
- Canada: Public-Private Partnership (PPP) based procurement.

Strengthen public safety and occupational safety norms

- Occupations where more stringent safety norms could enhance demand for MedTech: Construction, manufacturing, sports, etc.
- Example of strengthened safety normal leading to increased adoption:
    - The EU has stringent regulations requiring defibrillators in all commercial buildings
    - Led to higher usage rate of 12-59%, (0-7.9% in countries without regulations)

Key challenges:

- Around 80% of components for advanced devices are imported, including semiconductors and imaging sensors.
- Limited per capita use of MedTech in India.
- Sub-optimal Global Investment: Increased global investment could boost India's local ecosystem, fostering vendor development, upskilling talent, and strengthening supply chains.
- Significant room for improvement in healthcare access. Insurance and high ethical business standards are essential

Key recommendations:

- **Expand public insurance schemes and incentivize private ones** to cover MedTech-intensive sectors like home care, emergency care, and ambulatory care by 2029
- **Establish cross-ministerial procurement mechanisms** (PPOs, long-term contracts for railways, defense, etc.) by 2029
- **Mandate the inclusion of life-saving MedTech** products in public spaces and high-risk work environments by 2028

(NATHEALTH will provide comprehensive roadmap)

2. Software as a R&D Driver for Global Competitiveness

- **India's IT sector contributes ~7% to GDP (FY24)** with emerging competencies in cloud computing, AI, and cybersecurity–key for MedTech software
- India boasts a **talent pool of approximately 1 million existing IT professionals** skilled in these technologies and is expected to add another 2 million by 2030
- Software & AI Integration: Med-tech software innovation is a key growth driver, yet underutilized. **India has 1M+ skilled professionals in AI and cloud computing**, positioning it as a potential global leader
- **AI-based software development for medical devices** in India involves creating AI-driven applications to enhance medical devices' functionality for better diagnosis, treatment planning, and patient monitoring. Key areas include **diagnostic imaging, remote monitoring, personalized treatments, and surgical assistance**, all while complying with CDSCO guidelines
- This immense talent base positions India as a potential leader in med-tech software, aligning with the Make in India initiative's objectives and **offering significant opportunities for global impact**
- Hence, **strengthening the med-tech software R&D sector is essential**, as it not only capitalizes on India's vast talent pool but also creates substantial domestic job opportunities.
- By **retaining skilled professionals within the country, India can mitigate the risk of talent flight, ensuring that its workforce continues to drive innovation and economic growth**.

Key challenges:

- One of the key challenges in AI-based software development for medical devices in India is **data availability**. Access to large, diverse, and high-quality healthcare data is crucial for training robust AI models.
- Additionally, there are significant **ethical considerations** to address, such as ensuring transparency, fairness, and accountability in AI algorithms used in healthcare.
- Finally, the **market potential** presents a challenge as well as an opportunity, with the growing healthcare needs in India offering a significant opportunity for innovative AI-based medical devices.

Key recommendations:

- **By 2028 Recognition for med-tech software R&D,** such as tax breaks, research grants, fast-tracked approvals, local procurement mandates, testing platforms at hospitals, etc.
- The **government should encourage startups to create AI-based solutions** in the MedTech ecosystem by providing funding, creating innovation hubs, streamlining regulatory processes, fostering collaboration, offering tax incentives, enhancing data access, promoting awareness and adoption, and supporting skill development by 2026

3. Strategically Capitalize on Demand Tied to Affordability

Affordability

- ~2000-2500 new dialysis centres required year-on-year to deal with 2.2 lakh new ESRD patients per year
- High duties (27%-36%) on critical technologies & solutions like MRI, Linear Accelerators (LINAC) and CT scanners
- India is the largest importer of LINACs, holding a 95% market share, with imports growing 19% during FY24 despite high duties.
- Tariff measures like the Phased Manufacturing Program (PMP) have struggled to boost domestic production due to high investment barriers, small market size, and low profit margins, making advanced MedTech solutions costly and less accessible
- Bring down/adjust tariffs due to price sensitive market, especially in cancer care, dialysis, emergency care, ambulatory care (Class C/D particularly).

Refurbishment

- Lack of existing policies or specific provisions in Medical Device Rules, 2017 for the sale of refurbished products. In the case of imports, 38 refurbished high-end devices were allowed but, as of Jan 2025, Govt. has halted these imports due to lack of specific regulations for the same. MoH is working to constitute a high-level expert committee to address this and resume imports.

Key challenges:

- Price sensitive market
- Affordability of senior care, emergency care, ambulatory care (low insurance coverage, high OOPE)
- Limited market access for refurbished products

Key recommendations:

- **Implement a 5% GST slab and minimize tariffs** for MedTech by 2026 to promote affordability and market expansion
- The government should explore innovative technologies and provide a **2-year exemption period for local experimentation**, facilitating easier market entry for new products by 2029
- Establish clear guidelines and **fair-trade policies for refurbished MedTech products by 2027** to encourage accessibility and cost-effectiveness

4. Streamlining Compliance

Complex regulatory structure creating compliance bottlenecks for the healthcare sector and preventing ease of doing business

- **1400+** compliance tasks pertain to licenses/approvals/registrations to be obtained by the healthcare sector
- **~60%** of regulations applicable to healthcare industry are decentralized – leading to complexity of compliance due to lack of standardization
- **~25-30%** of compliances undergo change every year leading to a dynamic and complex regulatory structure

Key challenges:

- Mandated BIS certifications and compliance with multiple QCOs leading to delays in medical device registrations and approvals
- Different licensing authorities based on activity and class of device leading to multiple registrations and complex procedures and high response time by authorities to grant approvals
- Multiple regulations governing medical device labelling
- No defined timelines or guidance on seeking approvals for HCPs travelling for an event

Key recommendations:

- More specific and structural compliance recommendations in NATHEALTH EY report

5. Brand India for MedTech

Dedicated act for a MedTech nodal agency that can:

- Interface seamlessly with other arms of the govt. (e.g., regulatory bodies, industrial development agencies, research institutions, and other sectors such as defense)
- provide tech analogs and play a pivotal role in digital health ecosystem by supporting AI, telemedicine, health data integration, etc.
- work with federations like NATHEALTH to drive policy advocacy, market expansions, and capability-building
- set standards for VBP assessment, manufacturing, and compliance to ensure cost-effectiveness, quality, innovation, and global competitiveness
- work with export promotion agencies to boost exports, identify international opportunities, and facilitate trade agreements

- **Prioritize safety, quality, efficacy**
- **Transparency and predictability for investors**

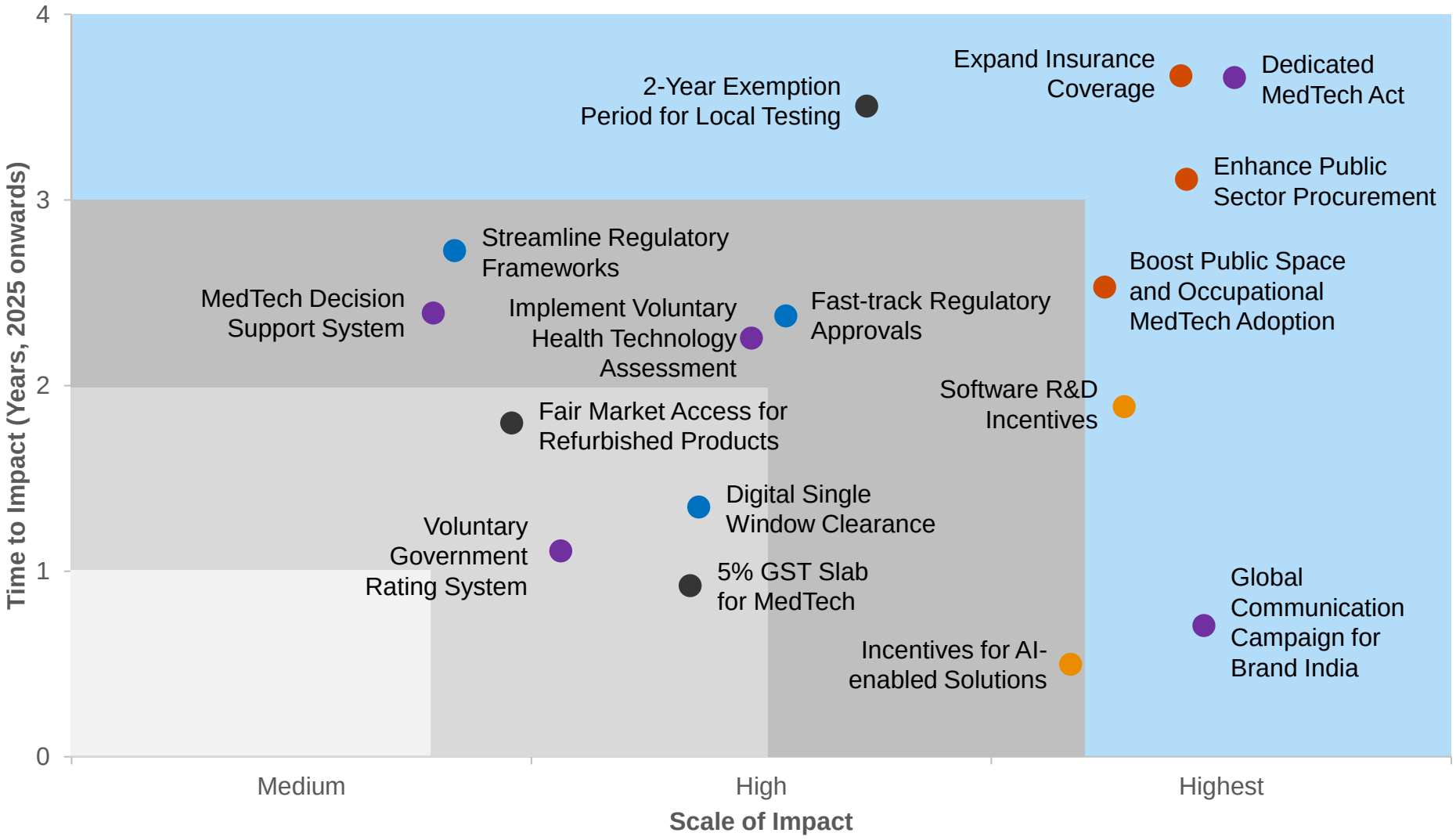
Key challenges:

- Lack of MedTech as a branding strategy for India - India needs to be known as a responsible, ethical, rule-following player in global MedTech.

Key recommendations:

- **Draft and pass a dedicated MedTech Act** to establish a nodal agency for overseeing safety, quality, and innovation in the sector by 2029.
- **Implement a voluntary government rating system** ("Brand MedTech") for better pricing, product positioning, and consumer trust by 2027
- **Develop a Decision Support System** portal to help interpret various MedTech policies and check compatibility with local and global standards by 2028
- **Implement Voluntary Health Technology Assessment** in India to enhance evidence generation for informed decision-making and cost optimization in the healthcare sector by 2027
- **Global communication campaign for Brand India by 2026**

Conclusion



Key Themes

- Domestic Demand Stimulation
- Software as a Driver of Global Competitiveness
- Capitalizing on Demand linked to Affordability
- Streamlining Compliance
- Brand India for MedTech

Thank you