The medical device industry in India
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Foreword

The Indian medical device sector, valued at USD 4.9 billion, is relatively small but has seen unprecedented growth in the last few years. Growing at a CAGR of 17% over the last five years, the sector is expected to continue witnessing double-digit growth with a CAGR of 15% in the coming decade.

From both the regulatory and domestic innovations perspective, recent changes in this sector, especially with the government's focus on the Make in India campaign, will cause a shift in the industry's structure, conduct and performance.

This report analyses the changing dynamics and environment of the industry, its impact on various players and the opportunities that are likely to arise in the coming years.

India is one of the top 20 markets for medical devices in the world and is the fourth largest market in Asia after Japan, China and South Korea. Socio-economic factors such as an increase in healthcare spending, potential for insurance coverage, increase in doctor's density and the un-served population are some of the driving factors for this growth. These factors lead to a greater requirement of healthcare facilities, which in turn, leads to higher demand for sophisticated devices and equipment.

The domestic medical device industry is highly fragmented, however it is yet dominated by large MNC's. Currently, this sector is import dependent with 70–75% of demand being met through imports. However, approximately 30% sof domestically manufactured devices are exported, with the Consumables and Disposables segment having the largest share. Out of the 800 medical device manufacturers in India, only 70–80 have a turnover in excess of INR 500 million. While multinational companies clearly dominate the market in high-end products, especially diagnostic equipment and instruments, domestic players have a noticeable presence in the low-priced, high-volume segments. In the last few years, domestic companies such as Opto Circuits, Biocon, Sushrut Adler Group, Perfint and Skanray have aggressively capitalised on opportunities and launched newer products. These companies are now shifting their focus from acquiring market share to market creation.

Presently, the sector is largely unregulated, with only 14 products notified and regulated as medical devices. Recently, the Indian government is in the process of taking steps to strengthen the regulatory and policy framework, infrastructure, research and development (R&D), and skill development. These changes are expected to increase opportunities for both domestic as well as international players. Companies with a strong product pipeline, wide hospital reach, and quality infrastructure will have an edge over others and will be in a better position to capitalise on their intrinsic value proposition.
The Indian Medical Device Market

The Indian medical device market is significantly smaller than other overseas markets. However, macroeconomic factors suggest a huge potential for double-digit growth in the Indian medical device sector. Upcoming developments in the regulatory and policy framework are expected to accelerate growth of the Indian medical devices sector at an estimated 10-year CAGR of 15%.

**Healthcare market**
USD billion

<table>
<thead>
<tr>
<th>Country</th>
<th>Market Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>2700</td>
</tr>
<tr>
<td>Japan</td>
<td>1000</td>
</tr>
<tr>
<td>China</td>
<td>500</td>
</tr>
<tr>
<td>Brazil</td>
<td>110</td>
</tr>
<tr>
<td>India</td>
<td>80</td>
</tr>
</tbody>
</table>

Source: IBEF Healthcare Report 2015, SKP analysis

**Indian healthcare sector - USD 80 billion**

- Hospitals: 77%
- Pharmaceuticals: 14%
- Medical Devices: 6%
- Diagnostics: 3%

**Indian medical device sector - USD 4.9 billion**

- Equipment and Instruments: 53%
- Consumables and Disposables: 27%
- Implants: 13%
- Patient Aids: 7%

Source: IBEF Healthcare Report 2015
Source: SKP analysis

<table>
<thead>
<tr>
<th>Product Segmentation</th>
<th>Players</th>
<th>Consumers</th>
<th>Supply Chain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment and Instruments</td>
<td>Domestic players: Low-price, high-volume products MNCs dominate in high-end products (technology, price and quality)</td>
<td>70% spend by private and 30% spend by the government</td>
<td>Purchase departments of hospitals and government tenders play a crucial role in the Equipment and Instruments segment</td>
</tr>
<tr>
<td>’Consumables and Disposables’ and ’Implants’ with 17% and 25% CAGR, respectively</td>
<td>Some MNCs have customised products for Indian markets with lower price point</td>
<td>Increasing consumer base specifically in the implants segment on account of increasing insurance penetration</td>
<td>Distributors and government tenders play a crucial role in Consumables. Surgeons influence decision-making in the case of Implants.</td>
</tr>
</tbody>
</table>
Untapped Potential and Future Growth Drivers

Rising income levels, an ageing population, increased prevalence of lifestyle-related diseases, and the government's commitment to provide healthcare services at a reasonable cost to both the rural and urban population are some of the factors attracting domestic and global players in the Indian medical device market.


- According to the International Monetary Fund, per capita income in India is estimated to rise to USD 2,672 by 2020 from USD 1,508 in 2013 adding to the already expanding middle-income group.

- India's population above 60 years was estimated at 104 million in the 2011 census and is expected to increase to 200 million by 2025, and to 300 million by 2050.

- Currently the government's per capita healthcare spend is 1.04% of GDP and is proposed to be raised to 2.5% of GDP by 2020.
Segmentation

The Indian medical devices sector can be broadly categorised into the following four segments:

Equipment and Instruments: USD 2.67 billion

- Diagnosing imaging and IV diagnostics forms major part of Equipment and Instruments with market size in excess of USD 1bn and USD 0.4 bn respectively. Approximately 51% of medical device imports are from the Equipment and Instruments category.
- Key products: MRI machines, CT scanners, ultrasound machines, dental drills, dental chairs, dental x-ray machines, etc.
- Key players: GE Healthcare, Philips Healthcare, Schiller Healthcare, Danaher Corporation, Mectron India, Roche Diagnostics, Accurex Bio-medical, Narang Medical, etc.
- There is great potential in low-end and mid-range systems purchased by small hospitals and facilities in rural areas.

Consumables and Disposables: USD 1.31 billion

- Syringes, Needles and Catheters form major part of Consumables and Disposables with market size in excess of USD 1bn collectively.
- Consumables and Disposables is the only trade surplus segment of the medical device sector with domestic players having a larger market share.
- Key products: syringes, needles, catheters, bandages and dressings
- Key players: Hindustan Syringes, Lotus Surgicals, Sutures India, B Braun, Beckton Dickinson
- Most of the requirements are met through domestic manufacturing.

Implants: USD 0.35 billion

- Implants segment is highly import driven (dominated by USA) and expected to grow faster than the other segments in the medical device sector.
- Few domestic companies in the Implants segment are offering customised designs for the Indian population gaining competitive advantage.
- Key products: knee and hip implants, artificial joints, dental fixtures
- Key players: Smith & Nephew, Narang Medical, Zimmer Holdings, J&J
- Domestic players are experimenting with proprietary technologies and technology tie-ups. Products customised for the Indian market may gain a competitive advantage.

Patient Aids: USD 0.65 billion

- Hearing Aids and Pacemakers form major part of the Patient Aids segments and constitute 70% of the market collectively.
- Import-driven segment: Most products are primarily sourced from Ireland, USA, Australia, Singapore, China and South Korea
- Key products: hearing aids, pacemakers and artificial respiration apparatus
- Key players: St Jude Medical, Shree Pacetronics, Medisafe International, Medtronics
- Significant potential for domestic manufacturing
Structure of the Industry
The Indian medical device sector is characterised by import dependency and a highly fragmented domestic industry. Presently, imports are preferred over domestic manufacturing mainly due to the inverted duty structure and the lack of favourable policy and regulatory framework.

Import Dependency
Segment-wise import proportions

<table>
<thead>
<tr>
<th>Segment</th>
<th>Indigenous Sales</th>
<th>Import</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumables</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>Equipment</td>
<td>10%</td>
<td>90%</td>
</tr>
<tr>
<td>Implants</td>
<td>25%</td>
<td>75%</td>
</tr>
<tr>
<td>Patient Aids</td>
<td>20%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Driven by cost competitiveness
Technologically advanced and competitive on account of inverted duty structure

Source: Beroe Inc

Highly Fragmented Domestic Industry
% share

- Fragmented Small Players: 65%
- Less than INR 100 million: 25%
- INR 100-500 million: 10%
- > INR 500 million: 10%

Currently there are around 800 medical device manufacturers in India.

Source: Association of Indian Medical Device Industry (AIMED)

Takeaway
With upcoming changes in the regulatory and policy framework and the inherent growth potential of the industry, this sector is expected to undergo a phase of consolidation.
Medical Device Clusters in India

Over the years, various medical device clusters have emerged across India. States have drawn strength from the availability of skilled/unskilled labour and accordingly developed state-level policies. The following figure highlights the strengths of the top states with medical device clusters.

1 **Haryana**
   - *Low-End Consumables, Dental Equipment*
   - E.g. Hindustan Syringes, Narang Medicals, Poly Medicure, BL Life sciences
   - **Strength**: Availability of low-cost unskilled labour

2 **Delhi**
   - *Medtech Innovators*
   - E.g. Stanford-India Biodesign program, Bill and Melinda Gates Foundation, Michael and Susan Dell foundation
   - **Strength**: Proximity to the central government

3 **Gujarat (Surat)**
   - *Stent Manufacturing*
   - E.g. Envision Scientific, Invent Bio-Med, Sahjanand Medical Technologies
   - **Strength**: The laser-cutting technology used in diamond cutting was modified in India to manufacture stents

4 **Karnataka**
   - *Insulin Pens, Medical IT, Cardiac Stents and implants, PCR machines*
   - E.g. Biocon, Medived, Skanray, Bigtec Labs
   - **Strength**: High-skilled labour, engineers and technocrats

5 **Tamil Nadu**
   - *Diagnostics, Critical life support systems, Ophthalmology*
   - E.g. Trivitron Healthcare, Opto Circuits, Perfint Healthcare
   - **Strength**: High-skilled labour, engineers and technocrats

**Takeaway**

The northern part of India is largely concentrated with low-end consumable manufacturers due to the availability of low-cost labour and policy incentives whereas most companies in the southern region manufacture high-end devices or develop technology for the same due to the availability of skilled labour.
**Trends in FDI and M&A Transactions**

- 50% of the USD 600 million FDI received in the last five years came in 2014 and 2015.
- Since 2010, the sector saw several M&A transactions though the average deal size has been below USD 10 million. Equipment and Instruments and Consumables are the two segments attracting most foreign investments.

**FDI Trends**

Recent changes in foreign exchange regulations with respect to the medical device sector has allowed 100% FDI in both greenfield and brownfield projects. This provides a great opportunity for foreign players to enter the highly attractive Indian market.

- USA, Europe and Japan are the key source countries for FDI in medical devices.
- The Equipment and Instruments, Consumables and Implants segments have attracted the most FDI.

**M&A and PE Funding Trends**

The sector, with its tremendous growth potential, has attracted significant private equity capital in the last five years.

- Companies such as Trivitron, Sutures India and Perfint Healthcare have received several rounds of investments from investors, reflecting continued faith in the sector.
- The Equipment and Instruments and Consumables segments attracted the majority of M&A and PE investments.
- In the coming years, financial investors would like to exit the investments in the companies, opening up significant growth opportunities for strategic partnerships.
Since 2010, there have been **64 M&A and PE transactions** attracting investments of around **USD 429 million** in this sector.

<table>
<thead>
<tr>
<th>Types</th>
<th>Segmentation</th>
<th>Some Deals</th>
</tr>
</thead>
</table>
| Mergers and Acquisitions | **No. of Deals : 23**              | ▪ Smith & Nephew acquired Adler Mediquip for USD 23 million in 2013.  
▪ Terumo Penpol Ltd acquired by Terumo Corporation for USD 17 million in 2013 (bought out the promoter and now it is a Wholly owned subsidiary of Terumo Corporation).  
▪ Cipla acquired Jay Precision Pharmaceuticals for USD 15 million in 2015.                                                                                       |
|                      | ![Segmentation Graph](image)       | ![Some Deals](image)                                                                                                                                                                                                                                                                                                                  |
| PE Investments       | **No. of Deals: 41**                | ▪ Fidelity Growth Partners and India Value Fund invested USD 74 million and USD 24 million in 2012 and 2014, respectively in Trivitron Healthcare.  
▪ Goldman Sachs invested USD 21 million in BPL Medical Devices in 2013.  
▪ Samara Capital invested USD 24 million in Lotus Surgicals in 2013.  
▪ Relisys Medical Devices Pvt Ltd got investments of USD 5 million from India Life Sciences Fund in 2015.                                                                                                                                                  |
|                      | ![Segmentation Graph](image)       | ![Some Deals](image)                                                                                                                                                                                                                                                                                                                  |
| PE Exits             | **No. of Deals: 5**                 | ▪ ePlanet Ventures Fund and Headland Capital sold stakes for USD 74 million and USD 24 million in 2012 and 2014, respectively in Trivitron Healthcare.  
▪ OrbiMed Asia Partners and Carlyle Asia Growth Partners sold their stake in Claris Lifesciences Ltd for USD 39 million and USD 27 million in 2014 and 2015, respectively.                                                                                   |
|                      | ![Segmentation Graph](image)       | ![Some Deals](image)                                                                                                                                                                                                                                                                                                                  |

Source: VCCEdge.com
Regulatory and Policy Framework

The medical device sector has witnessed consistent growth over the last six years (from USD 3.1 billion in 2009 to USD 5 billion in 2015). However, factors such as inadequate regulatory systems, non-alignment with global standards and the lack of quality product testing infrastructure are issues that hinder its progress. Furthermore, insufficient attention by policymakers and a complex tax regime have also been responsible for its underdevelopment.

Current Regulatory Regime

The existing regulatory framework for medical devices in India has been inadequate for a USD-4.9 billion industry. Currently, only 14 devices are notified as medical devices and have specific regulations. Other medical devices are treated as ‘drugs’ under the Drugs & Cosmetics Act, 1940 & Rules. As a result, the remaining medical devices have been subject to the restrictive code/laws of the pharmaceutical sector. Ambiguity in the clinical trial mechanism and the lack of specific regulatory framework to govern the manufacturing standards and quality control systems have resulted in a lag in product quality as compared to global standards. At the policy level, there is not much support for foreign exchange laws, duty structures, etc., which has resulted in an unattractive environment for investors and ultimately obstructs technological improvements and innovations.

Make in India

In September 2014, the Indian government launched the ‘Make in India’ campaign, with the objective of making India a global manufacturing hub; thus, bringing foreign technology and capital into the country. Medical device is one of the 25 focused sectors identified by the Indian government as a part of this campaign. Accordingly, a task force was formed to address industry issues and make recommendations on ways to assist the industry.

Formation of Task Force

The DoP constitutes a task force to identify issues relating to the promotion of domestic production of high end medical devices.

Make in India

PM Modi announces the Make in India campaign with focus on 25 sectors, including medical devices.

100% FDI Allowed

The medical device sector was carved out from the pharmaceutical sector thereby allowing 100% FDI under the automatic route, for brownfield as well as greenfield set-ups.

Draft Drugs & Cosmetics (Amendment) Bill, 2015 released

The Bill proposes to expand the scope of the Act to cover new areas and will “regulate the import, manufacture, distribution and sale of drugs, cosmetics, medical devices”. The amendment is likely to be approved soon.

National Medical Device Policy

The DoP has recently issued the draft National Medical Device Policy 2015, which sets out the regulatory structure for medical devices.

Takeaway

The regulatory framework for the medical device sector in India has been rudimentary for a long time, however the new government has taken various initiatives to reach the sector’s full potential. The government formed a task force and initiated the process of implementing its various recommendations such as separating medical devices from the definition of ‘drugs’, and allowing 100% FDI for brownfield and greenfield investments in the sector.
**Recommendations by the Task Force**

As a part of the endeavour to boost growth in the medical device sector, a task force was constituted under the chairmanship of the Secretary, Department of Pharmaceuticals (DoP). The prime objective of the task force was to address issues related to the promotion of domestic production of medical devices.

The task force reviewed the industry from the following perspectives:
- Sector overview
- Policy and infrastructure
- Regulatory environment

The task force studied and analysed the sector in detail and sourced comments from stakeholders as well. It recommended a host of policy, infrastructural and regulatory measures. The report, released in April 2015, talks about the envisioned ecosystem for the medical device sector.

The task force has acknowledged the need for infrastructural development and an appropriate mechanism for efficacy and safety testing is necessary to achieve growth. The recommendations aim at developing a complete ecosystem to support the medical device sector in India.

The recommendations covered eight areas and have been summarised below:

**Policy Support**
- Creating necessary bodies to drive the policies and the administrative department
- Creating an independent body with a permanent office and support staff to:
  - Act as a single window for bodies involved/investors in this sector
  - Provide access to all government departments
- Renaming the Department of Pharmaceuticals to ‘Department of Pharmaceuticals and Medical Devices’ with a separate post of Director for Medical Devices
- Preference to domestically manufactured medical devices for government procurement
- Additional preferences for medical devices manufactured under the MSME sector

**Infrastructure**
- Setting up manufacturing hubs/clusters/parks in the Public Private Partnership (PPP) model where the government invests in capital expenditure to develop the infrastructure and private players can bear recurring expenses that is proportionate to their usage
- Setting up medical device parks that can offer conducive infrastructure to manufacture medical devices
- Concessional power tariff for up to 5-10 years
- Single-window facilitating body for financing support from Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR), Department of Electronics and Information Technology (DEITY) and Department of Pharmaceuticals (DoP)
- Interest subsidy to Micro, Small and Medium Enterprises (MSME)
Validation Centre

- Setting up government-run, common medical device testing facilities in PPP mode for testing/evaluating medical devices
- Setting up Centres of Excellence (COE) to support product development, validation and certification of the medical use of the devices
- Strengthening the ‘Made in India’ marking in medical devices in line with international standards such as CE and FDA

Skill Development

The task force acknowledged the importance of skilled manpower and technology research in the medical device sector and accordingly addressed critical areas such as the skill gap and the importance of building a conducive environment for research and development activities.

Keeping in mind the issue of shortage of skilled labour, the task force recommended some long-term initiatives:

- The setting up of a Skill Development Committee to address the grave shortage of skilled labour in the sector
- Setting up committees and representation through National Institutes of Pharmaceutical Education and Research (NIPERs) and Healthcare Sector Skill Council, for identifying skill gaps and designing an appropriate curriculum for vocational training
- Setting up satellite campuses for training and job placements

R&D

The task force identified issues such as low R&D investments, the lack of policy and financing support for medical device start-ups. To boost innovation it recommends following:

- Setting up an IP exchange where technologies can be showcased and licensed for commercial benefits
- Development of incubation centres whereby start-ups can share facilities for research and development
- The government should provide seed capital and viability gap funding for research projects and start-ups
- Enhanced tax benefits for R&D activities such as providing a long-term view of 10 years for 200% of weighted tax deductions

Pricing Policy

The task force has highlighted the need for an appropriate pricing policy to ensure a win-win situation for the industry and consumers. It recommended that the inverted duty structure, one of the key factors for import domination in the sector, be modified to promote domestic manufacturing of quality medical equipments and devices

- Empowering the National Pharmaceutical Pricing Authority (NPPA) for fixing and monitoring prices
- Creating a separate Price Control Order for medical devices
- Developing an appropriate pricing policy for medical devices which ensure a sufficient return on investment
- An independent price control body regulating and monitoring prices based on the principle of value for money
**Duty Structure**
Modifying the inverted duty structure to promote domestic manufacturing

- Minimum/zero import duty on raw material and manufacturing equipment used in the medical device sector
- Introducing a prohibition or stringent restrictions to stop the import of second-hand diagnostic equipment
- Levy of taxes on the MRP to counter pegging MRPs at an unreasonably high rate

Keeping in mind the current pain points of the sector, the task force recommended the following changes to the regulatory framework:

- A separate chapter for medical devices in the Drugs and Cosmetics Act
- A dedicated regulatory body to devise guidelines and standards for medical devices and regulate various activities like sales and import of goods, quality standards assurance, assurance of availability and affordability of medical devices

**Regulatory Framework**

- **Pain points:**
  - Medical devices are subject to laws and stringent penal provisions relevant to drugs
  - Lack of regulatory guidelines for clinical trials
  - Lack of risk-based classification systems
- **The proposed changes can add to the industry's sustainability in the long term with the introduction of:**
  - Product quality standards
  - Clarity on mechanism of clinical trials
  - Rational pricing
  - Checks on industry malpractices
- **Current status of the amendments:**
  - The Department of Health and Family Welfare released the draft amendments to the Drugs and Cosmetics Act on 31 December 2014 to invite comments from the stakeholders. The goal was to table the draft during the Budget session of the Parliament in February 2015, however, the progress so far has been slow.

**Takeaway**
The government’s initiative of forming the task force is a huge step towards creating an efficient ecosystem for the sector. The task force has reiterated long-pending issues and suggested a clear path forward. It has addressed issues at both, micro and macro levels, providing clear guidance for domestic production and its promotion.
The Shift in the Medical Device Sector after Regulatory Changes

<table>
<thead>
<tr>
<th>Structure</th>
<th>Conduct</th>
<th>Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nascent regulatory framework</td>
<td>MNCs preferred to import and be distributors</td>
<td>MNCs fetch high margins focusing on high-end products</td>
</tr>
<tr>
<td>Lack of a conducive environment for technological innovations</td>
<td>Domestic companies continued to focus on low-end products and refrained from investment in R&amp;D</td>
<td>Domestic players focus on low-cost products resulting in low margins</td>
</tr>
<tr>
<td>Inverted duty structure</td>
<td>No investments made in manufacturing and R&amp;D infrastructure</td>
<td>Domestic players could never build competency in R&amp;D</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory and Policy Framework Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robust regulatory framework</td>
</tr>
<tr>
<td>Conducive environment for technological innovations</td>
</tr>
<tr>
<td>Focus on manufacturing and research in India</td>
</tr>
</tbody>
</table>

Source: SKP analysis

Takeaway
Looking at the regulatory frameworks before and after changes, we can see the transition of the domestic industry, which can now not only produce high-quality, low-end products but can also manufacture high-end products through the assistance provided by the government (through regulatory and policy changes) and technical collaboration with their foreign counterparts.

The regulatory scenario post change indicates the possibility of strong, sustainable and technically sound domestic industry with high quality standards and affordable pricing.
Market Entry Options in India

The Indian medical device sector offers tremendous opportunities for companies of all sizes across segments. Some of the government-led initiatives taken to boost the sector include 100% FDI in greenfield and brownfield investments under the automatic route, the Make in India campaign, the draft National Medical Device Policy laying down the new framework for the sector (which includes the regulator, price fixing authority), medical device parks providing special incentives, and fast clearances and approvals.

Indian medical device players can leverage upon new policies, regulations and infrastructure to tap various opportunities created such as technological collaborations, strategic alliances with international players to focus on relevant market for them.

While entering the Indian medical device sector, a company's market entry option is subjective, and depends on their global strategy and capabilities. There are various options to enter the market, with each one having its own advantages and enjoying certain benefits.

International medical device companies looking to explore the Indian market may initially acquire/need a distributor to market their products, whereas companies that intend to take advantage of low-cost manufacturing to export to other neighbouring countries may set up/acquire a manufacturing plant in India.

Often, selecting an option also depends on the business phase the company is in. New entrants/smaller players may initially prefer entering into alliances with domestic companies and gradually scale up directly whereas mature/larger players may opt to enter directly through brownfield or greenfield investments.

### Takeaway

The selection of an entry option depends on various factors such as:
- The company's global strategy
- Market opportunities for their product portfolio in India
- Access to human and capital resources
- Cost-benefit analysis – outsourcing manufacturing capacity to save cost
While the market entry option depends on various factors as cited above, some key points that companies contemplate while entering India are as follows:

**Greenfield Entry**

- **Low-cost labour**: Indian’s manufacturing wages are among the lowest in the world at approximately USD 1.5 per hour, which is lower than China.
- **Incentives and manufacturing zones**: Many state governments provide duty exemptions and tax holidays in order to encourage greenfield investments in their respective states. These exemptions and holidays are generally offered under designated manufacturing zones such as Special Economic Zones (SEZs).
- **Export hub**: Rapid economic growth provides a large domestic market for manufacturers. The domestic market is massive and is only going to get bigger with time. Many manufacturers look at India as their export hub for Southeast Asia, Africa and the CIS nations.
- **Build and commit**: This entry mode will provide the investor with greater control and the ability to implement a long-term strategy. The investor also becomes eligible to gain from government benefits. Moreover, companies create their own brand and culture and maintain control over them.
- **Free Trade Agreements**: Being a signatory to the ASEAN-India Free Trade Agreement (FTA), India provides manufacturers with access to Southeast Asian countries with benefits such as duties, customs cooperation, preferred access to markets, sourcing inputs at competitive rates, etc.

**Brownfield Entry**

- **Readymade set-up**: Entering through the brownfield route provides the company with an existing set-up with all the approvals and licenses in place right from the start, which can be leveraged for scaling the business.
- **Faster access to clients, vendors and product technology**: New customers help not only with economies of scale but also for cross-selling other products, thereby directly affecting the top line. The company can leverage the existing vendors and supply chain to increase its top line.
- **Access to an established market**: By entering through an acquisition/joint venture, the company immediately gets pan-India presence and quick access to the market. As mentioned above, existing and new customers help not only with scaling of operations but also for cross-selling other products, thereby directly affecting the top line.
- **Local knowledge**: The company gets the added advantage of having access to local knowledge and avoiding mistakes/hassles.

**Strategic Alliances**

- **Distribution reach**: Smaller and mid-market players keen on exploring the Indian market may get easy access to customers by entering into a distribution agreement. This gives them access to the market with lower capital expenditure. Subsequently, on achieving a milestone, the company may opt for the direct entry mode.
- **Manufacturing expertise**: Mid-market players keen on exploring the domestic and neighbouring markets may enter into a contract manufacturing agreement with a domestic player and leverage the local manufacturing expertise and low labour cost. This gives them access to manufacturing at a lower capital expenditure. Subsequently, on achieving a milestone, the company may opt for the direct entry mode.
- **Technology collaboration**: Many domestic companies are ambitious to grow but lack technological know-how. MNCs, through technological collaboration, can provide access to technology and produce high-quality but low-cost products.
Opportunities in the Medical Device Sector

Recent policy and regulatory measures undertaken by the government can bring tremendous opportunities for domestic companies as well as MNCs. The anticipated shift in the regulatory framework is expected to attract more funds and technology in coming years.

<table>
<thead>
<tr>
<th>Drivers</th>
<th>Opportunities for Domestic Players</th>
<th>Opportunities for MNCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Envisioned regulatory and policy framework (bringing standardisation and efficient administration)</td>
<td>Quality-focused domestic companies can capture market share of sub-standard players</td>
<td>MNCs can launch new products across segments</td>
</tr>
<tr>
<td>Conducive environment for technological innovations</td>
<td>Domestic players can get access to global innovations through technological collaborations</td>
<td>MNCs can leverage domestic players’ reach and their understanding of India’s market dynamics through strategic collaborations</td>
</tr>
<tr>
<td>Focus on manufacturing and research in India</td>
<td>Domestic players with international-standard infrastructure can explore contract manufacturing opportunities</td>
<td>MNCs can explore outsourcing opportunities to cater to the Indian as well as global markets</td>
</tr>
</tbody>
</table>

Success Stories

Several companies have grown and made a mark for themselves in the medical device industry, anticipating a shift in the structure, conduct and performance of the sector.

<table>
<thead>
<tr>
<th>Opportunities Tapped</th>
<th>Domestic Players</th>
<th>Multinational Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customised to cater to Indian patient needs</td>
<td>Smith &amp; Nephew plc, a UK-based multinational, entered the Indian market via the brownfield route by acquiring Sushrut Adler, a medical equipment manufacturing company. The India division developed an external fixator for the Indian market</td>
<td>A leading US multinational medical devices, pharmaceutical and consumer packaged goods manufacturer, Johnson &amp; Johnson, developed a knee implant at different price points specifically suited for the Indian market</td>
</tr>
<tr>
<td>Developed/manufactured locally, extended markets globally</td>
<td>Aravind Eye Care, a WHO Collaborating Centre for Prevention of Blindness, has developed low-cost intraocular lenses for Indian markets, however today exported globally</td>
<td>A large US medical devices manufacturer, Hollister, entered the Indian market via the greenfield route by setting up a world-class manufacturing facility exclusively for exporting to global markets</td>
</tr>
<tr>
<td>Penetration through cost-competitive pricing</td>
<td>Opto Circuits, whose USFDA-listed and CE-marked products are marketed in over 150 countries, offers cardiovascular interventional products, such as cardiac stents, body implants and monitoring systems, at nearly half the price of its competitors</td>
<td>A large Dutch technology company, Philips Healthcare, is using its recent acquisitions in India to develop and launch a low-cost catheterization laboratory for the Indian market and plans to take the product to other developing markets as well.</td>
</tr>
</tbody>
</table>
Conclusion

The Indian medical device sector is certain to witness impressive growth as access to healthcare facilities in the country remains limited at present. In the near future, the sector will be buoyed by a strong and robust regulatory framework. Currently largely underdeveloped, the regulatory framework will only act as a catalyst for growth once the proposed laws and policy changes are implemented. India’s government has awarded due attention to the sector by making it one of its priorities and swiftly following that up by allowing 100% FDI in the sector.

While the sector is currently import dependent with limited or no access to new technology, with the government’s improved focus and favourable policy, domestic players are beginning to give tough competition to MNCs in varied product categories. Many MNCs have started manufacturing in India and more are bound to come as long as the government continues to assist the sector in a holistic manner. With all of the upcoming market, regulatory, policy and technological developments, the industry is ripe to attract investments across the segments.
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Our Team

**Guljit Singh | Executive Vice-Chairperson**
A former Director of Hollister Inc, USA, Guljit has over 40 years of experience, with a focus on strategic growth, in all aspects of running a global business – business and quality regulations, setting up legal entities, acquisitions, restructuring, marketing, legal, financing, manufacturing, human resources, information technology, product development, land acquisition, government relations, etc. He played a major role in setting up three large entities in USA, Europe and Asia. His last major undertaking was a greenfield project to set up a world-class medical device plant in North India in record time and on budget.

**Deepti Ahuja | Partner**
With over 13 years of experience, Deepti heads SKP’s business advisory and consulting practice. She has experience in handling advisory assignments across several industries including banking, textiles, pharmaceuticals, manufacturing, services and non-profit entities. Deepti has handled several valuation assignments for various purposes including mergers, regulatory, joint ventures, acquisitions, goodwill and brand. She has led various due diligence assignments on behalf of leading multinational companies, private equity firms and venture capitalists and she has assisted several multinationals in establishing a presence in India.

**Saloni Jhaveri | Partner**
With over 16 years of experience in private equity and corporate finance, Saloni has executed several cross-border and domestic transactions involving mergers, acquisitions, joint ventures, private equity funding as well as entry-strategy assignments across sectors such as healthcare, retail, consumer and real estate. She has led deal teams to successfully close transactions involving the preparation and review of financial models and business plans, development of transaction strategy and deal structures. She has been involved in presentations to investors/clients, negotiation and drafting of letters of intent including key commercial terms, managing due diligence reviews, coordination with multiple advisers and counterparties.
About Us

SKP is a long established and rapidly growing professional services group located in six major cities across India. We specialise in providing sound business and tax guidance and accounting services to international companies that are currently conducting or initiating business in India as well as those expanding overseas. We serve over 1,200 clients including multinationals, companies listed on exchanges, privately held and family-owned businesses from more than 45 countries.

From consulting on entry strategies to implementing business set-up and M&A transactional support, the SKP team assists clients with assurance, domestic and international tax, transfer pricing, corporate services, and finance and accounting outsourcing matters, all under one roof. Our team is dedicated to ensuring clients receive continuity of support, right across the business lifecycle.

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