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August 23, 2024

NAVIGATING THE BOOM: RISE OF M&A IN HEALTHCARE

Despite a subdued growth trajectory in Mergers and Acquisitions (M&A) and Private Equity (PE) activities throughout 2023 and the early months of 2024, the Indian healthcare and pharmaceutical sectors experienced a significant surge in deal activity during the first two quarters of this year. The Indian healthcare sector alone recorded deal activity worth USD 4.1 billion, marking a substantial 57% increase in deal value compared to the same period in the previous year. This trend highlights the growing investor interest and confidence in India's healthcare and pharmaceutical industries, even as broader market conditions remain cautious¹.

The Indian healthcare sector is expected to continue its upward trajectory over the next two quarters, driven by increased demand and population growth in tier-2 and tier-3 cities. Reports suggest that the hospital industry in the healthcare sector is expected to see a revenue growth of 12 to 14% in 2024 due to increased occupancy and capacity building fueled by fund infusions.²

With this background, this article analyzes the trends to look out for in the Indian healthcare sector along with key factors to consider while evaluating an acquisition in the healthcare sector.

SECTORS TO LOOK-OUT FOR:

- **Hospitals:** The hospital industry, which includes multi-specialty and single specialty hospitals, nursing homes, and other healthcare delivery organisations, has been the industry with highest growth and the centre of deal activity in year to date in 2024. This trend is expected to continue in the second half of 2024 and the following years, with major focus being on increasing the bed capacity and expanding the geographical reach of such hospitals. As per reports, the private sector players in the hospital industry are expected to add approximately 30,000 beds at a capital outlay of at least INR 32,500 crores over the period of next five years.³ Hospitals, particularly single specialty hospitals with expertise in oncology, nephrology, fertility, and hematology have been focus areas for acquirers over the past few years. Consolidation and expansion into tier-2 and tier-3 cities have also seen an increase.
- **Preventive healthcare:** There has been a marked shift towards consumers proactively monitoring their health, particularly since the pandemic. As a result, diagnostic centres have become increasingly profitable. Wellness devices such as smartwatches, continuous glucose monitoring devices, etc. which provide individuals with trackable data about their health have also seen an increase in their utilization.
- **Medical Devices and Equipment:** Foreign Direct Investment (FDI) up to 100% under the automatic route is permitted for manufacturing of medical devices.⁴ The Indian medical device industry is predicted to be worth USD 50 Billion by 2030 with sufficient push from multiple government initiatives.⁵ Medical device companies catering Speciality devices are ripe for expansion as they have shown huge scalability. Many companies are looking for capital to expand manufacturing as well as research & development (R&D) facility.
- **MedTech:** In the past few years, the deal activity around healthcare sector was densely concentrated on the hospitals and pharma sub-sector with relatively very low focus on the medical technology (MedTech) space. However, with the rise of artificial intelligence (AI) along with technological developments in the healthcare sector, multiple companies have now started focusing on MedTech and the investors have shown key interest in this sector. There has been a slew of traditional medical devices companies acquiring innovative MedTech startups in the past few years to strengthen their digital capabilities. The Indian MedTech industry is expected to reach USD 50 billion by 2025.⁶
- **Pharmaceutical products:** India has historically been considered as the "pharmacy of the world" and has attracted substantial interest of international and domestic acquirers. As per the FDI Policy, 100% FDI is allowed in greenfield pharmaceutical sector under automatic route and up to 74% is allowed in brownfield pharmaceutical sector with above 74% being subject to governmental approval.⁷ Between financial year 2018 to financial year 2023, total FDI flow in the pharmaceutical sector was INR 43,713 crores.⁸ Biopharma companies are actively developing biologics and biosimilars.
- **Bulk drugs manufacturers:** The Indian bulk drugs market has benefitted tremendously from the disinclination to purchase from China that has become increasingly prevalent across the world. Concurrently, the Indian government has been actively promoting domestic manufacture of bulk drugs.
- **Companies involved in Digital Health:** Digital Health sector has grown very rapidly, and India has seen sudden surge in digital health start-ups providing services like telemedicine, AI-supported healthcare delivery, etc.

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Significant collaborations are happening in this space, where more than one start-up are joining hands to expand scope and scalability. There is flavor for acquisitions in this space.

KEY TRENDS AND POLICY INITIATIVES:

We have discussed below some of the key trends and policy initiatives that are likely to drive deal activity in the healthcare sector in India in the coming few years.

- The Government is in the process of overhauling the existing legal framework for drugs, cosmetics, and medical devices with an intent to provide a comprehensive legislation with provisions to regulate drugs, medical devices, cosmetics, clinical trials, over-the-counter drugs, and online pharmacies, among others. The harmonization of the laws and regulations surrounding the pharmaceutical and medical devices sector will act as an impetus for entities to explore the Indian markets and localize production and supply chain for their products.
- Government has instituted a committee to look into pricing reforms for drugs and medical devices to address ways to balance price and availability of essential medicines in the country while providing the industry with incentives to sustain growth and exports. A price moderation framework will incentivize and attract drug and medical devices manufacturers to undertake domestic manufacturing and to encourage fair competition in the market and to reduce reliance on imports.
- The Government has also formed a panel to examine the possibility of bringing nutraceuticals under the ambit of the drug regulator, instead of the food regulator considering the overlap ingredients and the therapeutic usage, it is likely that nutraceuticals may come within the purview of the drug regulator. The nutraceutical market in India is estimated to reach USD 18 Billion by the end of 2025 as compared to USD 4 Billion in 2020, according to industry data and has great potential for manufacturers and investors given that the industry is at a nascent stage in India.
- The Government in a move to ensure maintenance of the quality of drugs manufactured in India in line with the standards laid down by the World Health Organization, notified the Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products (GMP) to replace the existing standards provided under the Drugs Rules. This will ensure the quality of drugs manufactured in India are at par with international standards and will provide a jumping board for the drug manufacturing sector in the country for foreign manufacturers to meet their local and global demands. There is significant increase in contract manufacturing for formulations and bulk drugs due to these initiatives.
- The Make in India initiative has led to a growing focus on domestic manufacturing and local value addition for products and services across various industries in India. Foreign players have also started looking to acquire and setup shop in India and undertake manufacturing either directly or through contract manufacturers.
- National Policy on Research & Development and Innovation in the Pharma-Med Tech Sector and the corresponding Scheme for Promotion of Research and Innovation in Pharma MedTech Sector have been launched to transform India into a high-volume, high-value player in the global market. It incentivizes private sector capital infusion in research and development of new and innovative drugs and medical devices and encourages collaboration between academia and industry.
- The Government has also introduced various Production Linked incentive Schemes (PLI Schemes) for Promotion of Domestic Manufacturing of Pharmaceutical Ingredients and medical devices as well as Research Linked Incentive Schemes (The RLI Schemes). The PLI Schemes signify the shift of emphasis from volume to value-based innovation and production in the pharmaceutical industry. These are likely to boost interest of acquirers, encourage research and innovation and also enable the industry to develop futuristic products and ideas.
- The Ministry's scheme "Strengthening of Pharmaceutical Industry (SPI)" with a total financial outlay of Rs. 500 Crores (USD 60.9 Million) extends support required to existing pharma clusters and MSMEs across the country to improve their productivity, quality and sustainability.
- The Department of Pharmaceuticals has prepared an Umbrella Scheme namely 'Scheme for Development of Pharma industry.' which comprises of the following sub schemes:
 - Assistance to Bulk Drug Industry for Common Facilitation Centres;
 - Assistance to Medical Device Industry for Common Facilitation Centres;
 - Assistance to Pharmaceutical Industry (CDP-PS);
 - Pharmaceutical Promotion and Development Scheme (PPDS); and
 - Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS).
- Certain tax benefits are granted to venture capital funds registered with the Securities and Exchange Board of India (SEBI) that invest into certain pharmaceutical businesses. The exemption seeks to encourage investments flowing into venture capital undertakings engaged in the business of bio-technology and production of basic drugs in the pharmaceutical sector to support the growth of the sector in these fields.
- The Indian Council for Medical Research (ICMR) has introduced guidelines to encourage development, deployment and adoption of AI based tools in biomedical research and healthcare and is relevant to innovators, developers, technologists, researchers, funding agencies, etc. It will help guide the investors in the regulatory outlook and opportunities to invest in AI related healthcare models emerging in the market.
- With the launch of the Ayushman Bharat Digital Mission, the government is actively promoting the digitization of the healthcare ecosystem in India. The ABDM has established an open, interoperable, standards-based digital ecosystem. Given that private players can also integrate with this ecosystem, it provides a favorable environment for the rapid development of digital health solutions.
- Government has notified the Digital Personal Data Protection Act. This act is on the lines of GDPR and is going to be a game changer as it will protect every information including medical records. The rules under this act are awaited.

All these developments and initiatives have given significant impetus to the healthcare sector and specifically

KEY FACTORS TO CONSIDER DURING M&AS IN THE HEALTHCARE SECTOR:

- **Representations and Warranties:** Representations, warranties, and indemnities are key clauses to focus on while investing in the healthcare sector. Given that healthcare is a highly regulated sector, there are significant potential implications (both in terms of monetary, reputational, and criminal) for non-compliance with the applicable regulatory provisions. Hospitals, diagnostic centres, pharmacies are required to comply with various environmental laws such as Bio-Medical Waste Management and Handling Rules, 2016 obtaining the consent to operate under the Air (Prevention and Control of Pollution) Act, 1981 and Water (Prevention and Control of Pollution) Act, 1974. Additionally, targets undertaking clinical trials may be further required to ensure that they have a robust clinical trial policy in place. The implication of some of these non-compliances also extend to closure of the facilities of the target. In light of the same, the acquirers need to evaluate the commercial and the legal risk involved in investing in targets which are not compliant with applicable laws and basis the magnitude of risk involved, appropriate representations/warranties/ indemnities need to be negotiated and factored into the transaction documents.
- **Title Diligence:** In cases where the target is a hospital or diagnostic centre, it is important to determine if the hospital or diagnostic centres are constructed on a freehold land or leasehold land. In case of the latter, governmental leasehold land is subject to compliance with certain conditions such as compulsory provision of benefits to the economically weaker classes etc., minimum bed requirements or approval obligations (for change in control). In case the land is a freehold land, it is imperative to trace the title of the land to ensure that there are no claims against title at a later stage given that the land forms an integral part of the value of the target.
- **Outsourcing Agreements/Agreements with key employees:** As part of the due diligence process (particularly where the target is an hospital), it is important to review: (a) employment or consultancy agreements for key healthcare professionals who contribute to a substantial part of the revenues or goodwill of the target hospital and the rights such key healthcare professionals have vis-a-vis their engagement with the target and continuity of such engagement (for example rights of key professionals to receive sweat equity or employee stock options); and (b) outsourcing agreements for noncore activities (such as diagnostic services, waste management agencies etc.) given that potential liability on the target (monetary or otherwise) could arise based on the non-compliances by such outsourcing service providers.
- **Historical disputes:** During the legal due diligence stage for acquisitions in healthcare sector, it is pertinent to assess the historical and pending litigations to which the target is a party. Pending medical negligence cases against the key doctors of the target or against the target itself can lead to value deterioration of the target and the interest of the acquirer.
- **Anti-trust filings:** Assessment with respect to notification to the Competition Commission of India (CCI) is also another factor to be taken into consideration while structuring acquisitions of target in the healthcare sector. Determination of notifiability will be based on (i) if the target is exempted from notification based on De Minimis Exemption⁹; (ii) the target's asset size and turnover, and (iii) the rights package of the acquirers in the acquisition. Prior knowledge of the potential notification to/approval from CCI will provide transacting parties greater clarity in relation to purported deal timelines. Additionally, the Competition Amendment Act, 2023 (2023Act) introduces the "deal value" threshold for notification, pursuant to which notification to /approval from CCI will become mandatory for all deals valued above INR 2,000 Crore (approximately USD 246,498,400) (DVTThreshold). DVT Threshold is yet to be implemented, however upon implementation, this would be a key determinant for timelines and structuring of large-scale M&A transactions in healthcare sector. Additionally, for acquirers who do not have any overlaps with the target in healthcare sector, they also have the option to opt for green channel filing which is a deemed approval from CCI.
- **Regulatory issues and compliance with laws:** Given that healthcare sector is a highly regulated sector, legal due diligence on the operations of the target becomes a key item for an investor. In most of the transactions in the healthcare sector, a regulatory non-compliance or a pending regulatory issue with a regulator is a gating issue for a transaction. Given that such non-compliances can have an impact on the operations of the target, investors should be careful in taking into account the impact of identified non-compliances in the purchase consideration. Another alternative to such gating issues regarding non-compliances is to seek a specific indemnity from the sellers or the promoters of the target with respect to such items. It is also important to analyze if the target is subject to consent requirements for any of the licenses owned by the target. Whether the deal is structured as a secondary acquisition, primary infusion, or a business transfer, consent requirements in relation to change in control, change in shareholding, or assignment can be triggered under any of the licenses, government contracts, or lending arrangements.
- **Share title verification:** In case the acquisition is structured as a share purchase, regulatory issues with the share title of the target is another gating issue. During the legal due diligence, it is important to verify the share title of the target from inception in terms of whether the shares were issued and transferred in compliance with applicable laws (including all regulatory filings). Additionally, representations in relation to share title of such shares shall always be fundamental in nature to which no disclosures shall be made by the target. The risk of issues with share title decreases if the shares of the target are in dematerialized form given that during the process of dematerialization, title verification is conducted by the bankers.
- **Data protection issues:** The acquirers shall diligence the collection, processing and sharing of sensitive personal data by the target to avoid any implications under Digital Personal Data Protection Act, 2023. This is a key factor for targets involved in health insurance and MedTech sector.

In a country like India, with a booming economy and a large population, the healthcare sector plays a crucial role in shaping the nation's future. The surge in deal activity within this sector is more than just a sign of economic growth; it is a catalyst for significant improvements in healthcare infrastructure. The heightened focus on healthcare is driving development across the country, particularly in tier 2 and tier 3 cities. Here, we see renowned healthcare players acquiring local entities, bringing with them advanced facilities, infrastructure, and expertise. This trend is contributing to the creation of a more robust healthcare ecosystem, making quality care accessible beyond major urban centers. These acquisitions are fueling economic growth while enhancing the accessibility and affordability of healthcare for a

broadader population. Moreover, they are generating new employment opportunities, further contributing to the socio-economic development of these regions. In essence, the ongoing wave of M&A activity in India's healthcare sector is fostering a more equitable and comprehensive healthcare landscape, with far-reaching benefits that extend well beyond financial returns.

Nishith Desai Associates has represented several marquee players and institutional investors in the healthcare sectors in their acquisitions.

SOME OF THE KEY DEALS BY NISHITH DESAI ASSOCIATES IN THE HEALTHCARE SECTOR ARE AS FOLLOWS:

- 1. NDA represented Max Healthcare Institute Limited in its acquisition of Alexis Multi-Speciality Hospital Private Limited
- 2. NDA represented GIC Singapore in its investment in Asia Healthcare Holdings
- 3. NDA represented health insurance third-party administrator Medi Assist in acquisition of Medvantage
- 4. NDA represented health insurance third-party administrator Medi Assist in acquisition of majority stake in UK based Mayfair

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You can direct your queries or comments to the relevant member.

¹Pharma and Healthcare Deal tracker, Providing M&A and PE deal insights, Q2 2024, Volume 20.06, Grant Thornton Bharat, available at: https://www.granthomton.in/globalassets/1.-member-firms/india/assets/pdfs/dealtracker/pharma_and_healthcare_dealtracker_q2_2024.pdf

²Indian Hospital Industry, ICRA Report, December 2023, available at: <https://www.icra.in/Rating/DownloadResearchSummaryReport?id=5426#:~:text=ICRA%20expects%20private%20sector%20players,outlay%20in%20excess%20of%20~Rs.>

³Ibid.

⁴Consolidated FDI Policy, 2020, §5.2.27.3.

⁵P. B. Jayakumar, *Why Medical Devices Firms Seek Lifelines*, Fortune India, February 08, 2024, available at: <https://www.fortuneindia.com/long-reads/why-medical-devices-firms-seek-lifelines/115714>.

⁶Akriti Bajaj, *Industry Scenario, Healthcare*, Invest India, available at: <https://www.investindia.gov.in/sector/healthcare#:~:text=The%20Indian%20Medtech%20Industry%20was,health%20insurance%2C%20and%20medical%20equipment.>

⁷Consolidated FDI Policy, 2020, § 5.2.27.

⁸Press Information Bureau, *Cabinet approves foreign investment of up to Rs.9589 crore in M/s Suven Pharmaceuticals Limited*, September 13, 2023, available at: <https://pib.gov.in/PressReleasePage.aspx?PRID=1956906#:~:text=Total%20FDI%20inflows%20in%20pharmaceutical,in%20the%20last%20financial%20year.>

⁹De Minimis Threshold is an exemption to notification provided in cases where the asset of the target in India is lesser than INR 450 Crores and turnover of the target in India is less than INR 1250 Crores.

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