Investments in the Healthcare Industry in India

Trilegal

India | February 24 2026

Deal activity in India's healthcare sector has remained strong in recent years, reflecting growing investor confidence and opportunities within the industry.

In this article, we discuss some legal and operational issues inherent to transactions within the healthcare space in India to provide context for stakeholders navigating a highly regulated market. We then move on to discuss some significant developments and changes in the Indian regulatory landscape which could impact mergers and acquisitions (**M&A**) and private equity (**PE**) investments in the healthcare sector, among others, in India.

I. ISSUES FOR CONSIDERATION IN INVESTMENTS IN THE HEALTHCARE SECTOR IN INDIA

The healthcare sector, being highly regulated, presents unique complexities that necessitate a thorough understanding of legal, regulatory, and operational considerations. While general principles such as due diligence, foreign exchange related regulatory compliances, and deal structuring apply universally, healthcare transactions demand additional scrutiny due to sector-specific challenges. Below, we outline some key issues that we have come across which are relevant in the healthcare sector.

FDI in Hospitals with In-House Pharmacies: The Ancillary Operations Dilemma

Under the Foreign Exchange Management (Non-debt Instruments) Rules, 2019, (**NDI Rules**), foreign direct investment (**FDI**) is permitted up to 100% under the automatic route in sectors or activities that are not explicitly prohibited under paragraph (2) of Schedule I of the NDI Rules. The construction of hospitals is covered under the construction development sector/activity and is explicitly listed in the NDI Rules as a sector/activity into which 100% FDI is permitted, under the automatic route. However, this does not extend to the provision of healthcare services through the hospitals, which is treated as a separate category and is neither listed nor prohibited under the NDI Rules. Consequently, it has been interpreted that FDI in the provision of healthcare services by hospitals is also permitted up to 100% under the automatic route.

In this context, it is important to note that the NDI Rules include a separate category for FDI in multi-brand retail trading (**MBRT**), which involves the sale or retail of multiple brands under one establishment. Pharmacies that sell pharmaceutical products from various brands would typically fall under this category. While FDI in the MBRT sector is capped at 51%, investment in this sector also requires prior government approval.

While it is common for hospitals to operate in-house pharmacies as an ancillary facility, the mere fact that hospital services constitute the primary business of the entity does not, by itself, obviate the need to examine compliance with FDI conditions applicable to such ancillary activities. Under the extant FDI framework, sectoral

conditions are activity-based, and where an investee entity undertakes multiple activities, FDI requirements applicable to each such activity are required to be complied with. Market views on this specific matter are however divided, and we outline the differing perspectives below.

One perspective is that if a hospital operates a pharmacy on its premises and if the pharmacy's operations are secondary to the hospital's core healthcare services, such as contributing only marginally to overall revenue and primarily serving in-house patients, then foreign investment in such entity should not be classified as FDI in the MBRT sector. On the other hand, there is a view that pharmacies operated by hospitals would still be considered part of the MBRT sector, regardless of these factors, and FDI in the hospital space should therefore be subject to the foreign investment restrictions outlined in the NDI Rules for the MBRT sector.

In order to navigate this uncertainty, potential investors could consider assessing whether the target hospital has implemented measures that reinforce the ancillary role of its pharmacy operations, in relation to the hospital's core healthcare operations and services. For instance, the hospital could ensure that the pharmacy is confined to the hospital premises (rather than being road-facing) and limits its sales to in-patients and out-patients with prescriptions from in-house doctors. Additionally, and as a best practice, hospitals could display signage in their pharmacies to this effect. It is also crucial for investors to confirm that the revenue generated from the pharmacy constitutes only a small portion of the hospital's overall income. Potential measures to mitigate the uncertainty around the applicability of MBRT restrictions to such operations should be carefully evaluated on a case-to-case basis to determine the most effective approach. Another approach, though more complex, is to separate the pharmacy business from the hospital, by de-merging it into a separate entity. This entity must be held by resident shareholders and therefore cannot mirror the shareholding of the entity operating the hospital. This structural separation may address any concerns regarding compliance with FDI restrictions on investments into the hospital-run pharmacy (an MBRT activity) are addressed at the outset.

Challenges in meeting consent and intimation requirements

Healthcare and pharmaceutical businesses require multiple licenses and registrations from both central and state authorities. These may cover the sale, distribution, import, and export of pharmaceutical drugs, cosmetics, and medical devices under the Drugs & Cosmetics Act, 1940 (**D&C Act**) and its associated rules (collectively, the **D&C Regime**).

In the context of M&A and business transfers, many licenses are subject to prior consent or notification requirements. In certain cases, a fresh license must be obtained when there is a change in control, management, entity name, or other specified triggers under the D&C Regime. However, these requirements are dispersed across various rules and often embedded as "conditions of license" within individual licenses, without uniform criteria, timelines, or structured procedures. This lack of consistency makes it crucial to assess compliance obligations well in advance, to prevent potential delays or disruptions after the transaction closes.

For instance, the Drugs Rules, 1945 (**Drugs Rules**) requires licensees to notify authorities in the event of a "change in constitution". The Drug Rules further specify that the existing license will remain valid for only 3 months following such a change which can create significant operational challenges. In practice, obtaining certain licenses may take longer than the 3 month period, leading to a gap between the expiry of the existing license and the issuance of the fresh one. This gap could disrupt business operations and should be carefully considered when the licensee entity is undergoing a 'change in control', which may fall within the scope of a 'change in constitution', as discussed in the next paragraph. By contrast, the Medical Devices Rules, 2017 (**MD Rules**) offers a more practical solution by requiring licensees to notify authorities within 45 days and providing

them a 6 month window to apply for a fresh license. Unlike the Drugs Rules, the MD Rules also specify that the existing licenses remain valid until a decision is made by the licensing authority, therefore minimising the risk of business disruptions.

Further, there has been debate regarding the scope of the term "change in constitution" under the Drugs Rules. One view is that it should be narrowly construed to cover only events such as the conversion of a company from private to public, or a change in the entity's name. Others, however, interpret it more broadly to include changes in majority shareholding and control, such as the ability to make key decisions or appoint management. Both the MD Rules and the Cosmetics Rules, 2020 (**Cosmetics Rules**) have clarified this concept by introducing a definition for "change in constitution" which is broadly defined to include a change in majority ownership (i.e., more than 50%). Since the Cosmetics Rules, MD Rules, and Drugs Rules are all framed under the same parent legislation (i.e., the D&C Act), there seems to be an implicit legislative intent to standardise the definition of "change in constitution" across all 3 sets of rules. However, this definition has yet to be formally incorporated into the Drugs Rules.

Navigating non-compete restrictions and carve outs

Non-compete provisions are among the most heavily negotiated clauses in healthcare M&A transactions. For instance, where private equity investors are acquiring a majority stake in a target involved in the healthcare business, they often seek some form of a non-compete provision to protect their investment and prevent competition from key individuals or sellers or founders who may be exiting the business. In deals involving hospital chains which are predominantly run by doctor-promoters, investors are keen on protecting the acquired business's value by incorporating non-compete restrictions on founding doctors.

However, in such cases, completely restricting the sellers or former doctor-promoters from practicing their profession can unfairly limit their right to work. As a result, investors must devise innovative solutions that strike a balance between imposing non-compete restrictions and enabling the sellers or former promoters to continue practicing their profession within reasonable boundaries. This balance may be achieved through one (or a combination) of the following approaches:

· Geographical carve outs: Sellers can continue operations or make investments outside the target's primary geographical market, reducing the competitive overlap.

· Sector-specific carve outs: Sellers are allowed to invest or participate in related healthcare sectors that do not directly compete with the target's core business, such as healthcare technology or wellness services.

· Service-based carve outs: Sellers who are involved in healthcare education, such as delivering lectures at universities, may continue those activities.

· Passive investments: Passive investments are usually permitted, allowing sellers to hold minority stakes (for example, a 5% stake). Such minority investments would often be considered less likely to pose a risk of direct competition, as they may not provide the seller with significant control or influence over the business.

We have also seen situations where despite carve-outs which allow sellers to operate in competing areas, their ability to pursue new opportunities is restricted by a right of first opportunity in favor of the acquirer or target. In such cases, even when sellers are permitted to engage in certain specific competing sectors, the acquirer or target retains the right to evaluate and potentially invest in these opportunities - either independently or alongside the sellers. This restriction becomes particularly significant when the brand name remains with the sellers and is merely licensed to the target entity.

II. KEY REGULATORY DEVELOPMENTS

India's regulatory landscape is continuously evolving with several significant changes that will have implications across industries, including healthcare. Below are the key regulatory changes in recent years, which have the potential to affect M&A activity in the healthcare sector.

Overhaul of India's merger control regime

In September 2024, the merger control framework in India was substantially overhauled. Ministry of Corporate Affairs notified certain provisions of the Competition (Amendment) Act, 2023, along with issuing the Competition Commission of India (Combinations) Regulations, 2024, Competition (Criteria for Exemption of Combinations) Rules, 2024, Competition (Minimum Value of Assets or Turnover) Rules, 2024, and Competition (Criteria for Combination) Rules, 2024 (collectively, the **CCI Act**). One of the key changes is the introduction of the concept of a deal value threshold (**DVT**), establishing a new criterion to determine whether a deal will require prior approval of the Competition Commission of India (**CCI**).

Enforcement of the DVT criterion would mean that the prior approval of CCI would be required for a transaction where the 'value' (which is notably broad and encompasses all forms of consideration including payments for technology assistance, IP licensing, branding, marketing, and call options to buy shares) exceeds INR 2,000 crore **and** where the target has "substantial business operations" (**SBO**) in India. As per the CCI Act, the determination of SBO depends on whether the enterprise is engaged in digital services or non-digital services and has a nexus with India, and specific criteria has been set out for each. A digital services business qualifies as passing the SBO test if at least 10% or more of its global business users or end users are in India. For non-digital businesses, the threshold is met if their India Gross Market Value (**GMV**) for the 12 months preceding the trigger event or turnover in India during the preceding financial year accounts for at least 10% of the entity's global figures and exceeds INR 5 billion in the relevant period. Notably the INR 5 billion threshold for GMV or turnover does not apply to enterprises providing digital services, and CCI approval is required even in cases where the transaction would otherwise fall within the *de minimis* exemption.

This shift is significant as it introduces an additional regulatory requirement for high-value transactions that previously escaped CCI scrutiny due to asset or turnover-based exemptions. The change is expected to increase the number of notifiable transactions to the CCI. The new regime also applies retroactively to deals signed but not closed, or deals partly consummated, before the new rules took effect, requiring those deals to secure CCI approval before closure if required.

Notification of the Digital Personal Data Protection Act, 2023 and DPDP rules

The Digital Personal Data Protection Act, 2023 and Digital Personal Data Protection Rules, 2025 (together, **DPDP Framework**) introduce a comprehensive framework for the collection, use, and management of digital personal data. The DPDP Framework focuses on principles like fairness, lawful processing, and accountability, and governs the obligations of data fiduciaries, and rights of data principals, as well as the role of other stakeholders, such as data processors and consent managers.

In a key implementation milestone, the Ministry of Electronics and Information Technology notified the Digital Personal Data Protection Rules, 2025 on 13 November 2025, which operationalised the Digital Personal Data Protection Act, 2023 by prescribing procedural and compliance requirements. While certain provisions took effect upon notification, the DPDP Framework contemplates a phased implementation, with several obligations being subject to transition periods of up to 18 months to allow organisations to align their systems, processes and governance frameworks with the new requirements.

For a sector as data-intensive as healthcare, where sensitive personal information - including health records, medical histories, and insurance details - is regularly processed, the coming into effect of the DPDP Framework introduces new standards for data protection. Healthcare M&A transactions will need to respond to these evolving requirements in an agile manner, with due diligence likely to focus on data protection compliance.

Pricing for hospitals subjected to scrutiny

The Clinical Establishments (Registration and Regulation) Act, 2010 (**CE Act**) and the Clinical Establishment (Central Government) Rules, 2012 (**CE Rules**) were introduced in an attempt to unify the framework for hospitals, ensure adherence to minimum standards, and provide affordable healthcare to the public. However, given that health is a state subject in India, each state has its own laws and regulations governing healthcare institutions. As a result, the CE Act is not automatically binding across the country, and states must expressly adopt it. As of now, only twelve states and seven union territories have adopted the CE Act.[1][1]

The CE Rules grant the central government, in consultation with state governments, the authority to prescribe the range of rates for procedures and services charged by clinical establishments. However, for nearly a decade after the CE Act's enactment, no specific rates have been prescribed. Against this background, the Veterans Forum for Transparency in Public Life, an NGO, filed a public interest litigation[2][2] in 2020, seeking the standardisation of rates for various hospital services. During the course of the proceedings on 27 February 2024, the counsel for the petitioner contended that until a permanent solution is reached, the central government may notify Central Government Health Services (**CGHS**) rates as an interim measure. These CGHS rates are designed for serving and retired civilian central government employees and pensioners and are typically significantly lower than the rates charged by private hospitals. The Supreme Court of India directed the Department of Health to come out with a concrete proposal for determining the rates for hospital services, failing which the court will issue appropriate directions regarding the petitioner's request to notify CGHS rates.

This Supreme Court order raised concerns among private hospitals and investors, as the introduction of a band of rates could impact hospital revenues and commercial viability of healthcare institutions. While subsequent hearings have taken place, no final directions on rate standardisation have been issued to date. The manner and extent to which the government proposes to operationalise the Court's directions therefore remains to be seen, and will be closely watched for its implications on the healthcare sector.

Trilegal - Kosha Thaker and Niyati Khullar