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Asia Healthcare Due Diligence

By Michel Brekelmans

COVID-19 has turned the private equity (PE) industry upside down. Most firms are firmly focussed on ensuring the survival of their portfolio companies. Corporate investors are even more cautious in terms of major capital investments. But with almost \$400bn of dry powder available for new investment in Asia, PE firms will soon want to restart their investment activities. Over the past 5-10 years healthcare has represented a major focus area of PE activity in Asia. And global healthcare players have been increasingly active in Asia deal making driven by favourable demographic trends and growing wealth.

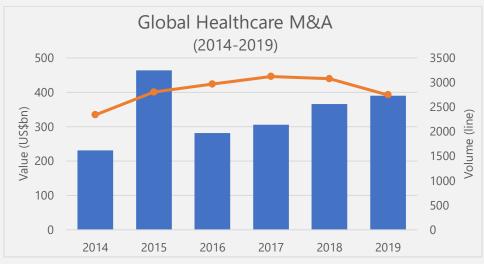
In this article we take a look at the growth of healthcare investing in Asia and particularly some key lessons to take onboard when embarking on due diligence of Asia healthcare targets.

The rise of healthcare M&A in Asia

Substantial growth in healthcare investments in Asia

There is traditionally a lot of activity in healthcare M&A; the deal volume is high and takeover sums are usually large: it is a typical carve-out industry where big pharma, medtech and biotech companies are continuously re-evaluating their portfolio products.

Total M&A value in the healthcare and life sciences sector increased by 7% compared to 2018 based on data from Refinitiv. In total, the sector raised USD 391 billion across 2,744 deals in 2019. Cross-border M&As raised USD 156 billion and accounted for slightly less than 30% of the total volume of M&A activity in the sector.



Source: Refinitiv

There were some eye-catching deals in 2019. For instance, Takeda, Japan's largest pharmaceutical firm, bought Ireland-based Shire for USD 77 billion — by far the largest-ever foreign buyout by a Japanese company. At the same time, a number of blockbuster mergers are pending. These include Bristol-Myers Squibb's USD 93 billion bid for Celgene, and the transaction between GSK and Pfizer to form a new world-leading consumer healthcare joint venture.

PE Investment in healthcare in the Asia-Pacific region has been increasing rapidly in recent years. According to data from Bain, PE investment in healthcare in Asia Pacific more than doubled in the 5 years to 2019 to \$11.5bn. This represents around 8% of total PE deal investment in the region.

Growth potential for
PE investment in
healthcare in Asia is
substantial

Asia's share of global PE healthcare investment (~\$80bn worldwide in 2019) is still relatively small, representing 14.6% of the global total. In comparison Asia's share of the global PE market (asset under management across all industry sectors) was around 25% last year, and Asia's share of global GDP (PPP) and world population is ~50% and ~60% respectively. This suggests there is ample catch-up growth potential for healthcare investing in Asia.

PE funds are looking for buy-and-build targets in new sectors. Pharma players with established products will attract investment, as there's no drug development risk. Plus, any uninvested products in their portfolios will represent growth opportunities as another factor driving acquisitions in this sector

Healthcare investment covers several sub-categories, including healthcare service providers (hospitals, clinics and diagnostic labs), pharmaceutical and biotech companies, medtech (equipment, devices and disposables) and health insurers. Traditionally, most deal flow is in the provider segment where investors are consolidating hospitals and labs into larger groups to drive efficiencies and quality of care.

Digital health is becoming an increasingly active segment of investment and the COVID-19 pandemic has accelerated growth of telemedice, remote diagnostics and a host of other, tech-enabled, products and service. We recently published a separate paper looking at digital health and PE in Asia (click here for paper).

Commercial and Operational Due Diligence issues for Asia healthcare M&A

Healthcare deals have characteristics that are not found in other sectors and need to be considered carefully

Due diligence is a necessary step in any transaction. Whether it is a clinical affiliation or a full sale merger, due diligence is conducted so both parties fully understand the other. Often times, the best due diligence process is one that is robust, involving substantial interaction and discussion between the parties, and resulting in a detailed understanding of the operational and commercial performance of the target.

Below is a discussion of key features of healthcare deals that require tailored approaches in the commercial and operational due diligence process. We have tried to highlight a number of key considerations but in reality, the issues differ considerably between pharma, medtech and / or healthcare service providers and a specific DD checklist needs to be developed for each target.

IP, regulatory and compliance: In most healthcare deals, the buyer is looking to acquire knowhow, IP and regulatory approvals and specific attention should be given to these areas during the DD process. Especially if the target is an early stage company of which regulatory approvals are still pending at the moment of sale, sellers often have a different valuation in mind than buyers. Commonly applied valuation methods in other industries will not be appropriate and we see that forecasts are commonly used to arrive at the purchase price. Parties

usually bridge such "valuation gap" by milestone and earn-out payments. The outcome of clinical trials, the moment of submitting requests to various regulators and the actual grant of marketing authorization of the product are usually triggers for those deferred payments.

Portfolio Commercialisation Status: Healthcare deals can involve products at various stages of development, and consideration should be given to the differences of each stage. A key point to consider before doing a deal is whether the product of the target company is pre- or post-launch.

Pipeline products could

be potential

blockbusters but face

significant uncertainty

in clinical trials

If the transaction is being done during the pre-launch phase this means that significant funding will be required for the further development of the product without any guaranteed income in the future. Furthermore the commercial due diligence needs to focus on forecasting the market potential of the product upon launch and over the lifecycle of the products. This involves assessing the perceived clinical benefits of the products versus existing treatment paradigms and the potential uptake of products or service under different pricing scenarios.

For companies with products already on the market we need to have an understanding of the patent expiry period as well as the risk of potential innovative competing products or services in development.

Biotech and the Probability of Success: If the target is focussed on R&D and in the development phase it is key to consider clinical trials in the due diligence exercise. This is relevant, for example, when we assist a buyer in acquiring a biotech company with one or two products in an early stage.

The review will be primarily focused on CRO agreements, data protection, authorizations, insurance and any collaboration agreements whereby the target has agreed to pool research and share data. Under existing collaboration arrangements, it is important to determine to what extent the target's IP is restricted.

The valuation of biotech with early stage pipeline products is complicated by the highly uncertain outcome of the various stages of the clinical trial process. It is essential for the buyer to have access to the details and preliminary results of ongoing studies, such as laboratory data. Regardless the outcome of future clinical trials can at best be an informed estimation. We would use historical studies on

probability of success at different stages of the clinical trial process to inform an 'estimated expected' valuation of pipeline products.

Service Considerations: for healthcare service providers such as hospitals, clinics or diagnostic centres, people are key to the service delivery and the due diligence process needs to take account of HR issues to ensure there is minimum disruption post transaction.

Deals with service providers need to assess risk of staff resistance to M&A

Doctors in a practice or hospital setting can sometimes provide the largest resistance to a transaction by not wanting to be a part of the acquiring entity. It is possible that the owner of the practice wants to sell as part of an exit strategy, but the doctors in the practice like their lifestyle, hours, and the current set-up with patients. A doctor in a seller's practice might have questions about the quality of care provided by the buyer and so there is no question that the physicians involved from the sellers' side have the power to quash a potential deal.

Infrastructure: IT Infrastructure is critical in today's healthcare industry. The decision to migrate the seller's information technology activities to the buyer's IT platform or to maintain the seller's legacy system is an important consideration. In most instances, the buyer will move the seller to the buyer's system. The transfer to the buyer's system will require a commitment of time and training. If the buyer is a PE firm they may not have ready IT solutions to impose on the target but nevertheless they may play an important driver to upgrade the target's IT capabilities as well as other operational improvements to improve performance of the business.

Competition: From a merger control perspective, there has been a high intervention rate in the healthcare sector. We have seen close scrutiny of pipeline products and the potential reduction of innovation that could be caused by an anticipated transaction, making innovation competition a key consideration when doing an M&A deal. Besides drugs, merger control may be further intensified in hospital mergers and mergers of independent treatment centres in the EU but Asia's fragmented landscape may be spared such scrutiny for the foreseeable future.

Impact of COVID-19 on healthcare due diligence

COVID-19 adds an additional layer of complexities to the healthcare due diligence process

Covid-19 is having a profound impact on global health systems. The disruption to normal health insurance and health industry operations has been dramatic and swift during this period of the appearance and continuing threat of COVID-19. In many cases, while hospitals and clinics have focused on COVID-19 treatment initially the focus has changed on how to keep their patient customers coming back albeit perhaps using virtual means and the rise of telemedicine has taken hold in the region.

Some pharmaceuticals are witnessing a surge in demand led by higher export of essential medicines, general public awareness and increase in funding and investments.

On the flipside, there are significant challenges with import restrictions from China/other regions, supply shortages and escalation in pricing, disruption in supply chains and an adverse impact of forex.

For M&A transactions going forward during the COVID-19 crisis, and for those occurring several years after it's over, PE and corporate investors will need to perform additional due diligence to evaluate whether and how well targets managed **legal compliance** during the pandemic. In particular, investors will need to determine if targets have properly relied on and implemented numerous regulatory waivers and other changes regulators issued in response to the pandemic.

Another critical area for review are the target's **financial projections**, especially around revenue and margin loss assessment due to closure of business activities, decrease in customer demand and / or customer loss. Many transactions include provisions to revise the purchase price at closing based on the financial position of the target entity. Management assumptions and computation of impact on historical and forecast business performance will need to be closely analysed for FY21, FY22 and FY23 with appropriate sensitivities.

Also, COVID-19 may result in significant **employee retrenchment**, suspension of pay, impact of technology on current business model, change in remuneration policies and severance pay expenditure. Further, run rate adjustment where salaries have not been paid or provided for any period due to COVID-19 will need to be considered.

Rental cost may be renegotiated by invoking force majeure clauses and there will be a need to assess revised agreements and potential disputes/ disagreements. Impact on rental costs due to fixed minimum payout instead of revenue share particularly for clinic and health / fitness centre operators should also be analysed. **Transportation and freights** costs may also increase substantially in short term due to higher demand and supply chain disruptions.

It is important to take stock of ongoing transactions and determine how best to move forward given the COVID-19 pandemic. This could mean pushing the transaction forward faster than anticipated, delaying the next step in the process or reconsidering the transaction in full. Whatever the decision for your organization, being aware of the possible next steps and analyzing how best to protect yourself in an uncertain future can be critical to long-term success.

In a fast growing and highly regulated market, healthcare deals have specific characteristics that are not found in other deals and need to be considered carefully:

- Pharma and medtech companies face uncertainties in clinical development and disruption from competing products.
- Service providers such as hospitals or diagnostic players need to specifically assess infrastructure, operations and human resource issues carefully.
- In digital health the issues are different yet again, for instance looking at the adoption curve for new technologies and solutions and alternative business models for commercial success.

COVID-19 has added an additional layer of complexities to the healthcare due diligence process. We help our clients identify and assess the unique issues that are relevant for specific deals so that buyers can make informed decisions in valuations and negotiations.

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