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HEALTHCARE & PHARMACEUTICALS ALERT

IN THIS ISSUE

The role of mergers and acquisitions in the pharmaceutical industry

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Health Market Inquiry: Competition Commissioner proposes interim solutions

The Competition Commission (Commission) released its 260-page report detailing the findings and recommendations of the Health Market Inquiry (HMI) in September 2019, a process which commenced in 2014.



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The role of mergers and acquisitions in the pharmaceutical industry

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A brief history of how the pharmaceutical industry developed

The history of the top ten pharmaceutical companies is characterised by such companies continuously reinventing themselves. By way of an example, in 2018, only one of the top ten pharmaceutical companies, Gilead, had a history of less than 100 years, which speaks to the length of time many pharmaceuticals have been in the market (Bieri "What Drives Mergers and Acquisitions in the Pharma Industry?" 2018 (https://www.contractpharma.com/issues/2018-01-01/view_features/what-drives-mergers-acquisitions-in-the-pharma-industry/) accessed on 27 August 2021). To further illustrate the evolution of pharmaceutical companies by way of M&A, consider that 60 of the pharmaceutical companies that existed in 1999 have been consolidated into 10 big pharmaceutical companies (Cha and Lorrigan "Why pharma megamergers work" 2014 (<https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/why-pharma-megamergers-work>) accessed on 27 August 2021). Moreover, 110 pharmaceutical companies have been consolidated into 30 in just

the last three decades (Davidoc "The History of Bio-Pharma Industry M&As, Lessons Learned and Trends to Watch" 2014 (<https://www.pm360online.com/the-history-of-bio-pharma-industry-mas-lessons-learned-and-trends-to-watch/>) accessed on 27 August 2021). Interestingly, although one often thinks of M&A in the pharmaceutical space occurring on a multi-national scale by default, this was not always the case. As Davidoc points out, the trend of consolidations among pharmaceutical companies started out with companies converging within their home countries first, and thereafter moving on to global scale consolidations when internal consolidation opportunities were exhausted. The more recent trends are spin-offs, whereby the parts of companies' businesses with different business models, revenue streams and profit-growth opportunities are separated into smaller entities. The slow growth of specific products of a business, and competing generic products is, amongst others, one of the driving factors behind the spin-off transaction model. We will now consider other driving factors behind M&A activity in the pharmaceutical industry.

What drives M&A in the pharmaceutical industry?

As with any other business, profit-making is central to the business strategy and models of pharmaceutical companies. M&A enables companies to streamline their operations by optimising overlapping workstreams and reducing overhead costs, which can contribute to profit growth. Furthermore, M&A plays a significant role in the overall growth and expansion strategies of pharmaceutical companies. Deals focused on creating new growth

The role of mergers and acquisitions in the pharmaceutical industry

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The ever-increasing costs associated with new drug development, which many pharmaceutical companies can no longer afford, has pushed pharmaceutical companies to find innovative ways of accessing funds for research and development.

platforms through consolidations are common, as they can provide companies with the capital required to fund new drug development, by providing access to new revenue streams (Alvaro, Challener and Branch "M&A: Fundamental to Pharma Industry Growth" 2020 (<https://www.pharmasalmanac.com/articles/ma-fundamental-to-pharma-industry-growth>) accessed on 27 August 2021).

The ever-increasing costs associated with new drug development, which many pharmaceutical companies can no longer afford, has pushed pharmaceutical companies to find innovative ways of accessing funds for research and development. For example, specialty pharmaceutical companies who are new to the market and often funded by venture capital or private equity firms, are often acquired by larger pharmaceutical companies thereby enabling such larger companies to access new generation technologies by outsourcing the research and development thereof. The entire drug development cycle is also being reinvented by this approach, as companies increasingly outsource processes that are capital intense and provide lower returns, such as the manufacturing of commercial and clinical trial products, as well as the management of clinical trials. This trend has had a knock-on effect on the supply chain end of the drug development process as consolidations and M&A activity amongst contract research organisations and contract development and manufacturing organisations follow suite (Alvaro, Challener and Branch "M&A: Fundamental to Pharma Industry Growth" 2020 (<https://www.pharmasalmanac.com/articles/ma-fundamental-to-pharma-industry-growth>) accessed on 27 August 2021).

The nature of the challenges faced by pharmaceutical companies is a strong driver behind M&A activity. In order to keep up with the rate of expansion of the critical size requirements of the pharmaceutical market segments, pharmaceutical companies were forced to consolidate in order to grow, as such growth could not have been achieved on their own. Furthermore, pharmaceutical companies continually need to keep up with advances in medicine, as pharmaceutical drugs derive their value from solving a problem which could previously not be solved, or offering something better than that which is currently available in the market, which requires cost-intensive research and development. There is also the challenge of competing with generic and biosimilar products and downward pricing pressure, as well as the challenge of reduced pipeline revenue streams due to the expiry of patents, and evolving regulatory requirements which lead to increased development costs, all of which drives cost-reduction mechanisms that can be achieved with M&A (Alvaro, Challener and Branch "M&A: Fundamental to Pharma Industry Growth" 2020 (<https://www.pharmasalmanac.com/articles/ma-fundamental-to-pharma-industry-growth>) accessed on 27 August 2021).

Despite the large volume of M&A activity that one sees in the pharmaceutical industry, there is a view that such M&A transactions in the pharmaceutical industry do not work optimally, due to the disruption caused by large-scale integrations across organisations, which negatively impacts on research and

The role of mergers and acquisitions in the pharmaceutical industry

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Despite the challenges faced by pharmaceutical companies, M&A transactions present opportunities for companies to find unique ways to adapt their business models in a manner that meets the market needs whilst at the same time optimising their operations.

development productivity (Cha and Lorrinan "Why pharma megamergers work" 2014 (<https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/why-pharma-megamergers-work>) accessed on 27 August 2021). There is also the fact that despite the cost-saving which can be achieved with M&A transactions, the complexity involved with executing such large-scale transactions can in themselves be costly. There are also various regulatory hurdles, especially in multi-jurisdictional M&A transactions, which need to be considered and overcome.

The South African perspective

The pharmaceutical industry in South Africa is regulated by the South African Health Products Regulatory Authority (SAHPRA), which is the regulatory body that has replaced the Medicines Control Council and is established by the Medicines and Related Substances Act 101 of 1965. The Pharmacy Act 53 of 1974 also applies to pharmaceutical companies in South Africa.

As mentioned above, evolving regulatory requirements are often one of the major challenges faced by pharmaceutical companies in terms of the cost and practical implications of complying with such regulations.

For example, marketing authorisations for products under South African law can take anywhere from 12-18 months to obtain from the SAHPRA. In most cases, for companies undergoing re-structuring

transactions, there is a need to obtain such marketing authorisations sooner. Various structuring options are available under these circumstances to achieve the economic benefit derived from the transfer of a pharmaceutical business prior to having obtained the relevant marketing authorisations. For example, a seller and purchaser may conclude an interim licensing arrangement for the continued marketing, sale and distribution of products by the seller of such business, which already holds the relevant marketing authorisations for such products, pending receipt of such market authorisations by the purchaser.

In such instances, parties are able to minimise delays in closing transactions which may be caused due to long lead regulatory approvals. In a rapidly evolving industry such as the pharmaceutical industry, time savings such as these are crucial.

Conclusion

Many factors drive M&A activity in the pharmaceutical space, as companies seek ways to grow and maximise profits. Despite the challenges faced by pharmaceutical companies, M&A transactions present opportunities for companies to find unique ways to adapt their business models in a manner that meets the market needs whilst at the same time optimising their operations.

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Health Market Inquiry: Competition Commissioner proposes interim solutions

Progress may have been paused by the pandemic, but it does appear that the Commission remains intent on ensuring that the years and money spent on the HMI do not go to waste.

The Competition Commission (Commission) released its 260-page report detailing the findings and recommendations of the Health Market Inquiry (HMI) in September 2019, a process which commenced in 2014.

Two years later, the legislative intervention required to implement the HMI recommendations is still awaited.

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Commission MOU with the CMS

In March 2021, the Commission entered into a Memorandum of Understanding (MOU) with the Council for Medical Schemes (CMS), which caters for, among other things, the provision of mutual support regarding the implementation of key HMI recommendations that impact the CMS. The MOU lists these as including the:

- development of a single base package for medical aid schemes (schemes) aligned with the review of prescribed minimum benefits (PMBs);
- review of the regulations relating to trustees, principal officers, and administrators to improve scheme accountability;
- multi-lateral tariff negotiation forum (MTNF) framework for PMBs and a reference price list for non-PMBs;
- designated service provider agreements that may raise competition issues;

- quality and outcomes monitoring; and
- any other matters requiring cooperation with respect to the HMI recommendations.

The MOU makes provision for the establishment of a joint working committee that will advise the CMS and the Commission and make recommendations on amendments to relevant or applicable statutes and deal with policy considerations.

Commissioner proposes interim solution

In August 2021, the Commissioner presented at the inaugural Health Funders Association (HFA) Lekgotla on the specific topic of the MTNF as a HMI recommendation for practitioners and funders.

Firstly, the Commissioner recapped the HMI's recommendations on this issue, namely that the MTNF:

- be established under the auspices of the Supply Side Regulator for Healthcare (SSRH);
- determine maximum PMB prices for practitioners and a reference price list for non-PMBs;
- review clinical coding to ensure that it aligns to tariffs;
- support subsequent value and risk-based bilateral negotiations; and
- allow for sharing of information to enable transparency in the negotiations.

Health Market Inquiry: Competition Commissioner proposes interim solutions...*continued*

In conclusion of the presentation at the HFA Lekgotla, and in an apparent nudge to the National Department of Health to commence the long-awaited reform, the Commissioner cautioned that the HMI recommendations were intended to be a package of interrelated interventions designed to promote systemic changes and that other relevant recommendations would still need to be implemented to achieve the objectives.

The Commissioner confirmed the HMI recommendations that bilateral negotiations can continue for funders and facilities, but that within three years, fee-for-service contracts should be replaced by alternative reimbursement models.

The Commissioner then confirmed that the establishment of the SSRH requires legislative intervention, but pending that an urgent solution is required to assist practitioners and funders in their tariff determination processes.

The interim solution proposed by the Commission is that, for the next two to three years, the industry make use of the exemption provisions in the Competition Act 89 of 1998, which allows for competitors to engage in conduct which would otherwise be deemed collusive. If an exemption is applied for by the participants to the collective

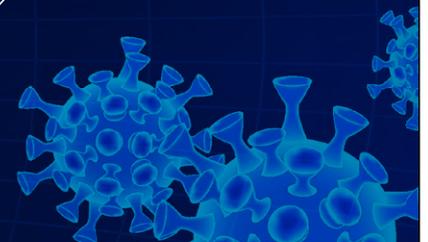
tariff negotiations and granted by the Commission, this would, according to the Commission, allow the industry to manage tariff increases (the Commission specifically cited a capped fee beyond which practitioners cannot charge) and commence collective discussions of the review of issues such as the clinical coding and PMBs, without fear of contravening the Competition Act. It remains to be seen whether the industry participants will follow the Commission's advice.

In conclusion of the presentation at the HFA Lekgotla, and in an apparent nudge to the National Department of Health to commence the long-awaited reform, the Commissioner cautioned that the HMI recommendations were intended to be a package of interrelated interventions designed to promote systemic changes and that other relevant recommendations would still need to be implemented to achieve the objectives.

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