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Business Development & Licensing Journal

NEW FEATURE

In Conversation with…

Leaders in Business Development

CONTENTS

Welcome

It would be remiss to begin this journey without first thanking and recognising the numerous achievements of my predecessor Sharon Finch, from whom I am privileged to take the editorial baton after a whopping 15 years and 32 issues. I would also like to acknowledge the unwavering support of Adam Collins and Linda Sterrett in helping me to pull this first issue together.

Aiming to keep our readers at the forefront of all things deal-making, we will continue sharing the latest insights and updates: in this season's issue, we break down 'market access' and understand why having real-world market access insights are highly valuable for licensing transactions (**page 4**). We also look, beyond the NDA, at the many factors that can impact the level of protection afforded to confidential information across various jurisdictions, including exchange control laws (**page 11**), and, in an exclusive double-feature from Taylor Wessing, we take a comprehensive look at what the new EU Medical Devices Regulation means for drug-device combinations (**page 18**), and how to prepare ahead of the IVDR becoming fully effective (**page 32**).

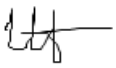
We also introduce a new feature, titled 'In Conversation With…', (**page 25**) which is intended to give readers an informal introduction to some of the leading professionals in the field. We are delighted to have had the pleasure of launching this inaugural feature with the brilliant company of Glenmark's EVP of Business Development, Marco Cerato, in a conversation that takes us through his background and career milestones and provides an insight into business development strategy at Glenmark, which we hope you will enjoy reading.

In summary, you'll find all of what you would usually hope to see with some additions. We want to keep the BD&L Journal interesting, relevant and helpful to our readership and so we invite you to share your feedback through completing a short survey (**page 36**).

Deal activity in the first half of 2021 more than doubled versus the same period in 2020, with a more than 400% increase when assessed by deal value (PwC analysis). The year had already seen newsworthy transactions including Jazz Pharmaceuticals' $7.2bn acquisition of GW Pharmaceuticals, and Nordic Capital's $846m acquisition of Advanz, and significant deal-making activity has continued well into Q3, with a shareholder vote expected imminently on Advent's $8bn acquisition bid for rare disease specialist Swedish Orphan Biovitrum. With the pandemic having exposed the sector's heavy reliance on manufacturers and CROs in countries hard-hit such as India, we have also seen much decisive action with companies closing deals to secure and de-risk their long term supply chains.

In July, the UK government revealed its ten-year 'Life Sciences Vision' which aims to apply learnings from the pandemic, where adjustment of red tape saw accelerated solutions developed and delivered for Covid-19, to other disease areas. Ambitions include boosting investment into R&D to 2.4% of GDP by 2027, improving clinical trial legislation and expediting regulatory assessments. We will be looking keenly to see how this might influence strategy for pharmaceutical and life science companies with a presence in the UK.

Finally, as many of us transition back to working in the office, later this month, the PLG will be holding its first face-to-face meeting in the UK since the pandemic began, and I hope to see some of you there. For our readers outside of the UK, I look forward to continuing to connect virtually at various events until next year's IPLS symposium in Brighton.



Umaima Ahmad
Editor

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Understanding the Value of Market Access Insights for Licensing Deals

Nerea Blanqué-Catalina, Raphaël Metrop, Romain Finas | Alira Health

The term 'Market Access' is used to describe all of the activities necessary to gain reimbursement for a product in a country. As a constantly evolving field, it is important to stay updated on the latest trends and tools, and to understand the value that a thorough market access analysis can add to an asset, particularly when it is being considered in a potential licensing transaction.

The origin of market access

The exact date of the origin of market access is unknown. Compared to other pharmaceutical activities, such as marketing or regulatory, market access is a relatively young activity. It was borne out of the need to understand the relationship between price, costs and healthcare resources. It can also be linked to the succession of economic crises, as every time there is a major crisis, new cost containment measures are created to keep healthcare costs at bay. There are articles that talk about pricing and fair pricing in 1998[1] that show that before the beginning of the millennia, pharmaceutical pricing was becoming an issue. We should consider that The Professional Society for Health Economics and Outcomes Research (ISPOR) was created in 1995 with the objective to advance the science and practice of health economics and outcomes research (HEOR) around the world. Therefore, market access, pricing and health economics are related and have grown in parallel over the years.

Moreover, around this time, health technology assessment (HTA) agencies began taking form in Europe, and they started to look not only at efficacy and safety, comparable to regulatory agencies, but at the cost effectiveness of a technology as well. The National Institute for Health and Care Excellence (NICE) was the first agency to appear in the European Union (EU) back in 1999[2]. Afterward, other HTAs were created both within and outside of the EU. Their main driver is to ensure medicines are affordable for all patients in order to improve resource allocation.

We are aware of the past and present status of healthcare; however, it is difficult to predict the future of health systems, healthcare priorities and the resources needed in the mid to long term. This knowledge is quite important in order to understand how the pricing and reimbursement landscape is going to develop; how payers are going to reach decisions, etc. and, it will be key for companies when they are making decisions regarding future pipeline products, as we will see later on in this article.

References

1 Lu, Z. John and Comanor, William S., (1998), Strategic Pricing Of New Pharmaceuticals, The Review of Economics and Statistics, 80, issue 1, p. 108-118.

2 Simon Walker, Stephen Palmer, Mark Sculpher, The role of NICE technology appraisal in NHS rationing, British Medical Bulletin, Volume 81-82, Issue 1, 2007, Pages 51–64, https://doi.org/10.1093/bmb/ldm007

Market access and pricing knowledge is constantly evolving. With the increase in the number of new therapies for rare diseases and genetic treatments, both of which have high prices, economic analyses and new innovative pricing models have been created in order to ensure the sustainability of the health system. Therefore, it is important that pharmaceutical companies have market access knowledge, understand payers, and keep up to date with the latest trends in order to make good business decisions.

What does market access really mean?

Market Access is often used as a general concept to describe all the activities necessary to gain reimbursement in a country; these are known as market access tools. Market access tools are prepared with payer input; companies that have these tools ready before launch are able to optimise the pricing and reimbursement (P&R) timelines for their [drugs/therapies], resulting in improved patient access to medicines in a given country.

The typical set of tools for market access (see **Figure 1**) includes:

- a **global value dossier** with specific messages that will resonate with payers at the time of pricing negotiations;
- an **objection handler document** that has been drafted to answer all possible questions that payers may ask during price negotiations;
- a **global launch pricing strategy** with specific recommendations on price trade-offs and on possible discount agreements or innovative pricing agreements with health authorities; and
- a set of **health economic tools** that will allow payers to understand if a product is cost-effective, or to demonstrate that a technology has a positive impact on a payer's budget. Cost-effectiveness and budget impact models are the most commonly used and well-known, but there are many more that can be prepared depending on the clinical trial design and the impact of a product.

When to start thinking about market access

The market access discipline has evolved from how it functioned in the mid-nineties. Experts have learned that not considering the payer's view is a strategic mistake as the price of a molecule may not reflect the assumed price. Our experience is that pharmaceutical companies have learned the hard way that there will be a price to pay if a payer's view is not taken into account from proof-of-concept and at every stage of the life of a drug (see **Figure 2**).

Figure 1 | The Market Access Set of Tools

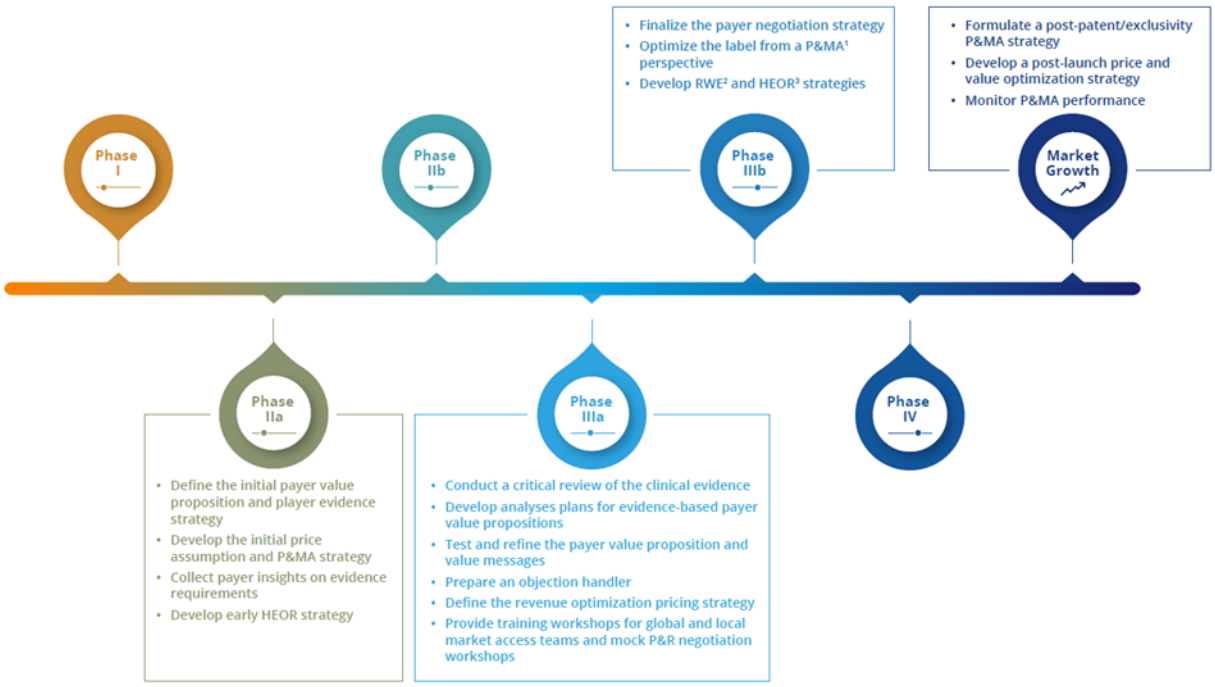

Figure 2 | List of Market Access Missions Along the Product Development Chain

P&L: the link between market access and licensing

Profit and Loss (P&L) is defined as the financial report detailing a company's past, present and future ability to generate sales and manage expenses in order to create profits. By nature, this tool allows both a potential licensee and a potential licensor to clarify the amount of remaining investments required to make a certain asset, the potential licensed asset, reach the market, and, as well, the expected level of revenues, margin and profits this asset will generate once it is commercialised on a territory-by-territory basis.

The P&L is, therefore, the only way to fully translate a pharmaceutical development programme into a return on investment (ROI)-based and financially-valuable opportunity. It is the main, not to say the only, bridge between Research and Development (R&D), Marketing & Sales and Business Development functions; the reason why its use is deeply connected to licensing practice.

That being said, and as detailed in **Figure 3** below, given that market access helps determine the target product profile of the potential licensed asset, which significantly impacts the design of its development plan and therefore, the amount of required clinical investment as well as the time it needs to be commercially launched, market access insights are influencing the "L" part of the P&L: the Loss.

However, considering that market access also helps determine the expected reimbursement status and selling price of the potential licensed asset, both of which significantly impact its potential market shares and related revenues, market access insights are also influencing the "P" part of the P&L: the Profit.

Thus, when it comes to licensing, market access cannot be ignored!

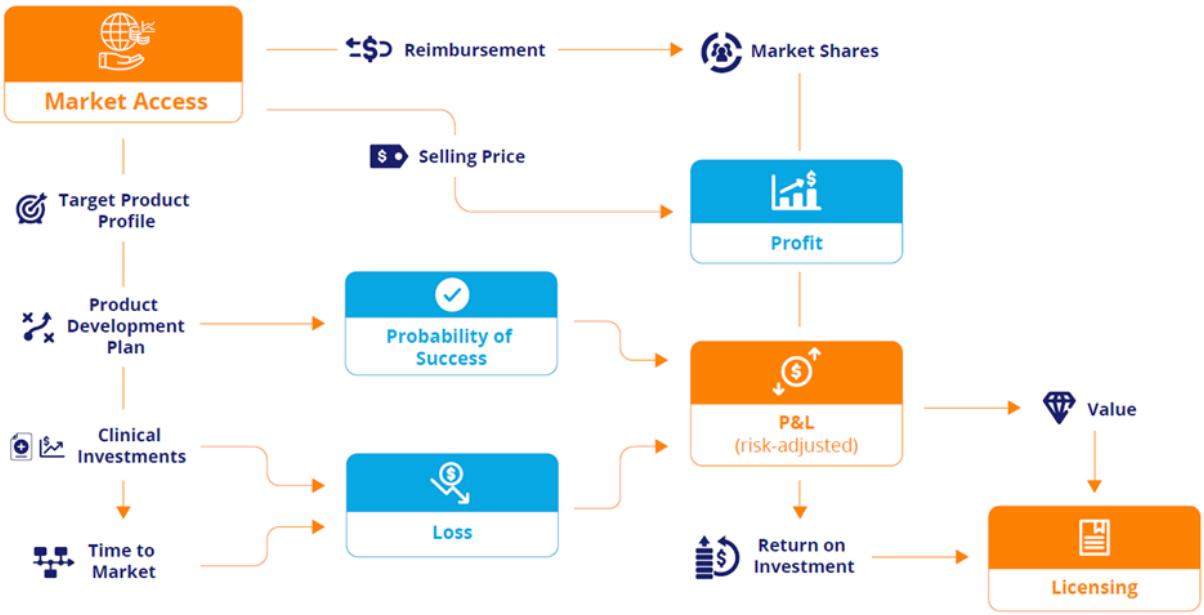

Figure 3 | From Market Access to Licensing Through P&L

Consequences for licensing deals

In every licensing opportunity for an asset that has not yet been launched in the territory of interest, whether because it is still an R&D-stage candidate, or because it is part of the international development strategy of a commercial-stage product, the licensed asset needs to be prepared and assessed from a market access and pricing perspective.

For the future licensor, performing comprehensive market access research is the best way to build a solid and factual presentation of the asset to be licensed, including an ambitious but still credible business plan reflecting the payer's point of view, to raise potential partner interest.

For the potential licensee, adding a market access analysis to the due diligence phase is the best way to justify the financial terms of the license agreement to be signed, by thoroughly assessing the asset's ability to generate an acceptable ROI in the future.

Whatever your position on the deal, adding a market access angle to the preparation, presentation, evaluation, and negotiation of a licensing opportunity, is essential to reaching success.

A step forward: Real-World Evidence (RWE), a mix of big data, market access and digital

Since the 2000s, the use of data generated by the healthcare system (electronic medical records, payers, claims, medical devices, etc.) has become instrumental for market access strategies. This so-called "Real-World Data" (RWD) enriches the value of clinical trials with a picture of the practice, outcomes, and costs within a daily care routine.

Depending on the quality, representativity of the data, and reliability of the collection process, Market Access and HEOR Departments regularly use RWD as insight for value dossiers (unmet needs, treatment pattern, burden of the disease, etc.) or the value demonstration in post-launch studies (from a clinical endpoint or health economic perspective).

Pharmaceutical companies have an alternative to leveraging RWD. They can choose to either access a ready-to-use database or generate a fit-for-purpose source, a decision which depends on the benefits and limitations of each solution.
A ready-to-use database, often accredited by HTA bodies or the European Medicines Agency (EMA), offers better statistical power (66 million patients in the Système National des Données de Santé [SNDS] database in France, 60 million patients in the Clinical Practice Research Datalink (CPRD] in the United Kingdom [UK], etc.). However, it brings inevitable limitations due to being a predetermined catalogue.

On the other hand, fit-for-purpose sources bring more flexibility in terms of data choices and a smaller population scope. Costs remain a critical factor in decision-making: using existing databases is cheaper than developing a bespoke data source upfront, which involves resources to populate a clinical form.

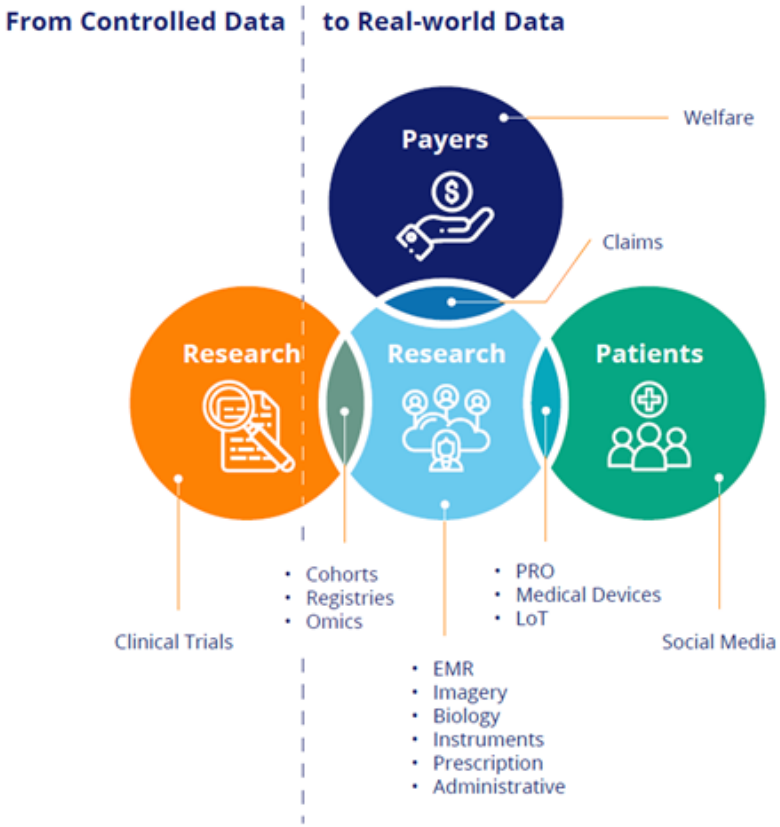

Figure 4 | From Controlled to Real-world Data

However, digital and artificial intelligence (AI) is now disrupting the data collection process, offering more possibilities to customise datasets based on existing data. AI tools can produce quick reviews of data available within a hospital, facilitate patient inclusion and automatise research from a population through textual data structuration.

Digital adds the patient's voice as well, with new digital applications collecting their experience or continuously monitoring data captured from devices.

Managing access to, and co-investing in, real-world data has become a new competitive advantage for pharmaceutical companies. It requires a great sense of foresight, and best practice shows that it starts as early as Phase III. Partnering with HTA bodies to validate sources and methodologies becomes key to maximising this new but promising investment area, Real-World Evidence.

Conclusion

It is strongly recommended to perform a systematic and full market access and pricing assessment when preparing or assessing a licensing opportunity, taking into account the payer's point of view.

Furthermore, it is recommended that every Business Development & Licensing (BD&L) team obtains basic knowledge of the main market access concepts presented in this paper to ensure they can at least understand the rationale behind questions, suggestions, and feedback from market access stakeholders during the preparation, presentation, evaluation and negotiations of a licensing deal.

There are new emerging practices that will shape the future, such as RWE. Real-world data, big data, translated into real-world evidence are a trend in the pharma industry. Pharmaceutical professionals will need to get acquainted with the basic concepts of this practice so they can be up-to-date with our rapidly evolving industry and can both improve and optimise decision-making within their companies.

Authors

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