Have you optimized your Market Access Efforts?

Market access has been a hot topic in pharma for several years now. But while most companies have made the leap to putting payers and other market access stakeholders at the forefront of their thinking, have they adapted their internal structures and key capabilities accordingly? Francesca Boggio and Andrea Sobrio report.


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Dividing companies into two broad 'buckets' — mid-sized/biotech companies and Big Pharma — industry consultants Executive Insight recently conducted research into how companies organized their market access capabilities. Although some commonalities between the two were found, pipeline structure, financial challenges and scope of activity differed markedly.

What do MA departments include?

We found that previously distinct departments are now commonly working together as a single market access offer. Frequently, where health economics and outcomes research may have previously sat separately to pricing and reimbursement, these departments now usually form the central core of market access capabilities. In Big Pharma, companies also incorporate new areas of activity such as healthcare systems monitoring, tendering, contracting, scenario modelling, real world data generation, health policy and patient advocacy.

How are MA capabilities structured?

A key question facing any pharmaceutical company is where market access should sit within the company — marketing, regulatory, medical affairs or corporate?

The majority of companies we reviewed place market access under their commercial operations/marketing umbrella. We may be seeing a trend towards market access replacing marketing as the lead in the commercialization process; such is the importance of payer audiences. The cannibalization of marketing by market access is likely to continue, but will depend on fostering genuine leadership and marketing skills among market access teams.

The second key question facing companies is whether to structure the market access capability by therapeutic area or by market. To an extent it depends on the specific objective; for example, value dossier creation lends itself naturally to a therapeutic area focus while a payer partnership programme should be designed around country clusters.

The companies we researched tend to specialize by therapeutic area, with the purpose of facilitating global reimbursement strategies for each one and there is no particular difference between mid-size and Big Pharma.

When is market access involved in a product lifecycle?

To facilitate global reimbursement strategies, it is now vital to consider market access during the early-stage development and clinical trials for a new product. In most companies, market access strategy had previously been developed separately from regulatory and brand strategy and the two were often combined just before launch.

The involvement of market access must start in early-stage drug development in order to take economic as well as clinical value into consideration. Clinical trials

and observational studies should have both clinical and economic endpoints to support economic arguments in future payer negotiations.

Our research has shown that market access is becoming more closely linked to R&D — certainly for Big Pharma anyway — implying that payer-driven data is being generated at an early stage. And observational studies — for so long clinical trials' poor relations — may now come into their own as payers seek real world evidence (RWE).

Companies also emphasize the importance of sharing health economics and cost information with payers as soon as possible so they can co-create the best reimbursement strategy for a new product.

Global, regional or local? The significant differences in local health systems often make the translation from global to local quite challenging. In addition, company size can dictate different sorts of challenges. A mid-size/biotech company may have limited resources and a limited number of products in the pipeline, both of which make consistent market access capabilities difficult to implement across geographies. Big Pharma on the other hand has challenges associated with complexity, multiple layers and a lack of true central coordination. This is where a regional competency can potentially add real value.

While global resources are well established, not all companies have started to hire local resources or have established fully-fledged MA capabilities. Therefore, often at a local level, market access duties are performed or coordinated by regulatory, marketing or sales functions.

It seems clear that companies struggle with coordinating reimbursement activities across broad product groups and geographic areas. Levels of interaction between countries and/or between HQ and local staff vary widely by company.

In the below table we summarise three broad levels of sophistication of pharmaceutical company market access capabilities, with Level 3 being the ideal, best practice scenario which the industry may be evolving towards. The blue line maps approximately where midsized/biotech companies currently reside, and the orange line where the 'Big Pharma' companies are currently, based on our research.

	Level 1	Level 2	Level 3
What Market Access includes	Health Economics and Outcome Research	Health Economics, Outcome research integrated with Pricing & Reimbursement	Health Care system intelligence and monitoring, Tendering & Innovative contracting, Health policy and patient advocacy added to the previous level
How MA capabilities are structured	Under Regulatory or Corporate Affairs with a strong focus on technical aspects	Under Marketing and with a focus on Therapeutic Area	Under the broader umbrella of Commercial Operations (possibly as an independent unit) and with market focus
When MA is involved in the product lifecycle	Phase III but especially Pre Launch and Commercialization phase	Phase IIb and III	Target selection and pre clinical identification
Where the main responsibilities lie	Mainly Global	Global with Regional supporting and facilitating the build up of capabilities at local level	Fully fledged Global, Regional and Local MA organization with clear split of responsibilities
Who implements the MA strategy at local level	Sales Reps sometimes accompanied by marketing or medical	Account Managers (sales reps with enhanced MA knowledge and skills)	Market Access Account Managers in collaboration with other functions (Integrated approach)

Current status observed in mid-sized / biotech companies

Current status observed in Big Pharma companies

Who are the new profiles needed in MA?

The rise of integrated account management (IAM) in recent years has been one of the defining changes in the pharmaceutical industry's response to the complex healthcare environment and the ever-changing requirements of payers. The industry is no longer selling just products — it now sells solutions, and it does to a broader audience than just prescribers — a very different proposition from the past.

Our research showed that the need for an IAM strategy has been well adopted by the industry at a local level. But anecdotally the feeling is there is work to be done. Often, account managers are yet to be recognized as senior decision-making people within their own companies. This undermines their ability to make autonomous decisions with key customers. In addition, alignment needs to improve between account managers and commercial functions to provide a seamless customer experience.

There is no doubt that account managers are an important innovation for the pharmaceutical industry, but the skills and processes still need to be refined, and the personnel selected judiciously and trained fully. In addition, the role of KOLs/key influencers cannot be forgotten as they still play a critical role in the commercial and

reimbursement success of a product.

Is there an optimal approach?

There is no 'one size fits all' solution for market access. Several factors — including existing company structure and levels of management, size of company and number of products and types of therapeutic area — will fundamentally affect how a company can optimally structure a market access capability. However, the priorities are slightly different for mid-size/biotech companies compared to Big Pharma

Our research suggests that the former should concentrate on creating an optimal organizational structure, gather the right resources, optimize the management of payer stakeholders through integrated account management, and finally generate the necessary evidence to support economical value of their product. Meanwhile, Big Pharma, who should already have the capability build issues covered, should focus more on effective and innovative ways to include market access into the early stage of product development with the help of real world evidence.

Optimizing organizational structure

In our opinion, a global organization should deliver the central strategy and value proposition and the key data to support it. A regional organization should ideally be in place to coordinate and manage any local complexities, and to provide launch sequences, guidelines on pricing, intelligence on the market reimbursement strategies and a toolbox to manage it all. Finally, local resources are needed to adapt the strategies and implement the programs locally.

At a local level, we suggest designing the organization according to local market archetypes. This way it should be possible to optimize resources where systems are centralized and deploy them where systems are regionalized. Also, the skills that companies would need to factor in are different in highly sophisticated markets with established HTA processes, compared to other markets where the decision is still very much driven by effectiveness only. With countries clustered in this way it is not only easier to structure effective and efficient MA departments but also to adapt the global market access strategy accordingly.

Integrated management of access key influencers.

We suggest the implementation of a cross-functional (Regulatory, Marketing, Medical, and Sales) integrated account management process to allow for appropriate management of market access stakeholders (reimbursement bodies, payers, HTA agencies, hospitals, etc). Typical activities to align would be the production of an integrated brand plan, the identification and profiling of all relevant stakeholders, the understanding of their needs in terms of solution, the planning and execution of cross functional programs and the actual engagement with the influencers and their networks to cascade the value messages.

Early integration of RWE

Market access is relevant at all stages of a product's lifecycle, from the lab to lifecycle management. Proving the value proposition is arguably as important as proving the clinical outcome. As early as Phase IIa, successful companies can identify unmet needs in the market and by Phase IIb/III, trial designs are adjusted if necessary. These activities and the preparation of the reimbursement and regulatory dossiers are increasingly supported by the creation of RWE — observational data incorporating information outside of controlled trials to create insights on diseases, products, and patient populations.

Early integration of RWE in the standard process of data generation has proven to be a successful strategy for many companies. This can help to meet payer's needs and inform R&D decisions, and also to enhance internal efficiency and support drug safety. In fact, the role of RWE in the future will include: conditional access, post launch label changes, risk management programs, lifecycle pricing, and usage.

The implementation of RWE studies requires both tight collaboration with the scientific community (co-creation) and the set up of processes and capabilities inside the company.

Conclusion

The pharmaceutical industry is carefully building effective market access capabilities. But setting up a company to roll out a market access strategy optimally is clearly beset with challenges, particularly generating evidence to support the reimbursement dossier, managing key influencers in an integrated way and translating global strategy into meaningful local implementation. Real world evidence, integrated account management and appropriate organizational design may help to facilitate this situation.

About the authors

Francesca Boggio is a manager and Andrea Sobrio is a partner at Executive Insight, a consulting company focusing on the pharmaceutical industry.