

Organization of the Pricing and Market Access Function

Success factors for organizational set-up, operational effectiveness, and talent management, including specifics for German affiliates

Stephan Schurz und Maximilian Rödter

Simon-Kucher & Partners, Bonn and Cologne

Abstract

As the pharmaceutical industry faces price pressure and a challenging payer environment, realizing the full value of a drug becomes an ever more challenging endeavour. In order to succeed in this environment, pharmaceutical executives and managers are looking to shape effective and efficient organizations. In this article, the authors focus on the optimal organization of the Pricing and Market Access (P&MA) function. They highlight success factors for organizational set-up, operational effectiveness, and talent management for the P&MA function in general and also discuss specifics for P&MA teams in German affiliates.

Zusammenfassung

Organisation der Pricing- und Market-Access-Funktion: Erfolgsfaktoren für Organisationsstruktur, Zusammenarbeit und Abläufe sowie Talententwicklung

Angesichts des steigenden Preisdrucks und der wachsenden Anforderungen vonseiten der Kostenträger stellt die Realisierung des wirtschaftlichen Potenzials innovativer Arzneimittel eine immer größere Herausforderung dar. Um in diesem Umfeld erfolgreich zu sein, bedarf es einer effektiven und effizienten Pricing- und Market-Access(P&MA)-Funktion. In diesem Artikel wird ein strukturierter Ansatz zur Optimierung der P&MA-Funktion vorgestellt. Die Autoren beleuchten Erfolgsfaktoren für die Organisationsstruktur, Zusammenarbeit und Abläufe sowie Talententwicklung. Neben generellen Erfolgsfaktoren werden auch Spezifika für P&MA-Teams in Deutschland betrachtet.

Introduction

The Pricing and Market Access (P&MA) function plays a critical role throughout a drug's lifecycle. During clinical development, P&MA input is crucial for prioritizing drugs which deliver the highest value and for shaping clinical trials based on payer requirements. From early development to beyond loss of exclusivity, the P&MA function supports optimal pricing and market access which lay the foundation for patient access and commercial success.

With pharmaceutical executives and managers looking to optimize the organization and operations of the P&MA function, fundamental questions emerge. Is the P&MA function set up in the right way? Do P&MA professionals focus on all relevant activities at the right time?

Are the required P&MA competencies covered and what is needed for a sustainable talent management in P&MA? These topics are outlined in this article building on the experience and expertise Simon-Kucher & Partners has developed through numerous projects in this area.

Throughout the article, the authors highlight organizational success factors which are applicable on the global, regional and local level. Since the introduction of the "Pharmaceuticals Market Reorganisation Act" in Germany (Arzneimittelmarktneuordnungsgesetz – AMNOG), P&MA has become an increasingly challenging and complex endeavour further raising the importance of organizational excellence in German affiliates. Consequently, specific best practices for P&MA teams in Germany are highlighted.

Pricing and Market Access Excellence

P&MA Excellence rests on three pillars: organizational set-up, operational effectiveness, and talent management (fig. 1).

■ Organizational set-up

The organizational set-up of a P&MA function provides the foundation for P&MA activities on the global, regional, and affiliate level. It is defined along the organizational dimensions structure, reporting, and sizing.

Structure and reporting on the global and regional level

The P&MA organization structures in top 20 pharmaceutical companies frequently combine elements of functional and matrix design. Each structure is unique as its

characteristics have evolved over time driven by the company's strategy, portfolio, corporate culture, and history of mergers and acquisitions (fig. 2).

A variety of parameters can be used to assess the organizational set-up of the P&MA function on the global and regional level.

Visibility and impact: The proximity of the P&MA function to the CEO supports the elevation of P&MA topics onto the executive agenda. In many companies, the highest P&MA representative is at least three steps below the CEO as depicted for "Company A" and "Company B". Establishing an Executive Vice President (EVP) who is responsible for P&MA and is only two steps below the CEO, as shown for "Company C", allows for increased visibility of P&MA-related business questions.

P&MA capability development: In many successful companies all P&MA activities are overseen by one senior executive. This approach allows for effective P&MA capability building and minimizes redundancies in executed tasks. This set-up also enables companies to leverage P&MA opportunities arising in the context of a broader product portfolio more easily.

Alignment of P&MA and evidence strategy: Best-in-class companies guarantee that P&MA and Health Economics and Outcomes Research (HEOR) work hand-in-hand to enable payer-rationalized trial design which ultimately maximizes the P&MA potential of a drug. Consequently, companies such as "Company C" establish a single Senior Executive who oversees global P&MA as well as global HEOR. In cases in which HEOR has a different reporting line, e. g., for "Company A", it is particularly important to institutionalize cross-functional collaboration between P&MA and HEOR to guarantee that separate reporting lines do not lead to misalignment between evidence strategies and P&MA requirements.

Cooperation with company-internal business partners: A business unit driven set-up of P&MA teams, as shown for "Company B", naturally links P&MA to the respective commercial teams. In case of a less institutionalized link between P&MA and commercial teams, it is crucial to establish regular touch points between both sides to avoid "silo mentalities" and the perception of P&MA being distant from the business.

Cooperation between P&MA teams on the global and regional level: An optimal organizational set-up between P&MA teams on the global and regional level enables alignment on key objectives, a systematic exchange of information as well as sustainable talent management across both levels, including job rotations and succession management. Consequently, as shown for "Company C", many successful P&MA organizations establish a dotted reporting line between regional and global P&MA.

■ AUTHOR



Stephan Schurz

is a Partner at Simon-Kucher & Partners and works in the Life Science division at the company's headquarters in Bonn, Germany. He specializes in the development of market introduction and competitive strategies, price optimization and value perception management for innovative pharmaceutical products. In addition, he plays a leading role in Simon-Kucher's market access operational excellence activities. Stephan has worked on projects for a variety of pharmaceutical and biotech companies. Over the years, he has worked on projects covering numerous developed and emerging markets. Prior to joining Simon-Kucher & Partners in 2007, Stephan studied business administration with a focus on strategy, organization and marketing at the University of Marburg, Germany.

While there is not one ideal organizational structure for a P&MA function, optimal solutions exist on a company-individual level. Any solution should consider the status quo of the organization as well as the company's strategy, portfolio, and corporate culture.

■ Organizational structure and sizing for P&MA teams in Germany

In German affiliates, five P&MA functional areas can frequently be identified:

- Market access and dossier development for The Institute for Quality and Efficiency in Health Care (IQWiG) and The Federal Joint Committee (G-BA)
- Strategic pricing and price negotiations with The Head Organization of the Association of Statutory Health Insurances (GKV-SV)
- Operational pricing (including price management for established products)

■ AUTHOR



Maximilian Rödder

is a Manager in the Life Science division of Simon-Kucher & Partners in Cologne, Germany. While being at the firm, he has supported a number of leading pharmaceutical and biotech companies in various business capacities, including launch and life-cycle pricing, value story development, early market potential assessment as well as organizational excellence. Maximilian has worked in a wide variety of therapeutic areas and has gained experience in a number of healthcare markets including the EU-5 and the US. Prior to joining the Simon-Kucher team in 2014, Maximilian earned a B.Sc. and a M.Sc. in business administration from the WHU – Otto Beisheim School of Management.

■ Figure 1



Pricing and Market Access Excellence framework (Source: All figures were created by Simon-Kucher & Partners).

- Regional payer management (including individual sick fund contracting, physician associations)
- Hospital payer key account management and contracting (including terms and conditions)

To ensure a consistent P&MA strategy and a seamless execution, most best-in-class companies locate all of these functional areas within one organizational unit. Thus, the German P&MA leadership can manage all P&MA activities holistically – from list price to net price, from early development to beyond loss of exclusivity.

Some rules of thumb for the appropriate size as well as the degree of specialization of affiliate P&MA teams can be deduced from business practice. As a general guide, a company should employ about 5–6 P&MA full time equivalents (FTEs) per 100 million Euro yearly revenue in Germany. This includes all P&MA related jobs which range from market access to strategic and operational pricing, contract management, and payer field force/payer key account managers. For a company with yearly revenue of 500 million Euros, this would lead to a P&MA team of 25–30 professionals who would be capable of handling all five functional areas. Such a specialized set-up is favourable for companies which have several products in their portfolio and a number of product candidates in their pipe-

line. For smaller companies and (biotech) companies launching their first product in Germany, a less specialized set-up would be appropriate. In such a case, a variety of these tasks is typically outsourced to external service providers with the necessary expertise and specialization in the respective P&MA field. Nonetheless, best-in-class companies with a smaller P&MA presence in Germany still make sure to understand all payer requirements as early as possible and have a dedicated team with the appropriate overview to steer the relevant P&MA activities and therefore lay the foundation for successful price negotiations and commercialization.

Operational effectiveness

The key questions needing to be clarified to improve operational effectiveness focus on the “What?” “When?” “How?” and “Who?” of P&MA activities. Best-in-class companies clarify these questions for all areas of P&MA activities and throughout the entire lifecycle of a drug – “from cradle to grave”.

Activities

“What?” relates to the scope of P&MA activities that are necessary for successfully developing an asset from a P&MA perspective. It is crucial to make sure that resulting de-

liverables are aligned with expectations from internal business partners. In fact, Simon-Kucher observed that best-in-class companies regularly assess whether all P&MA deliverables optimally contribute to commercial success and if any gaps in terms of activities and deliverables exist.

Processes

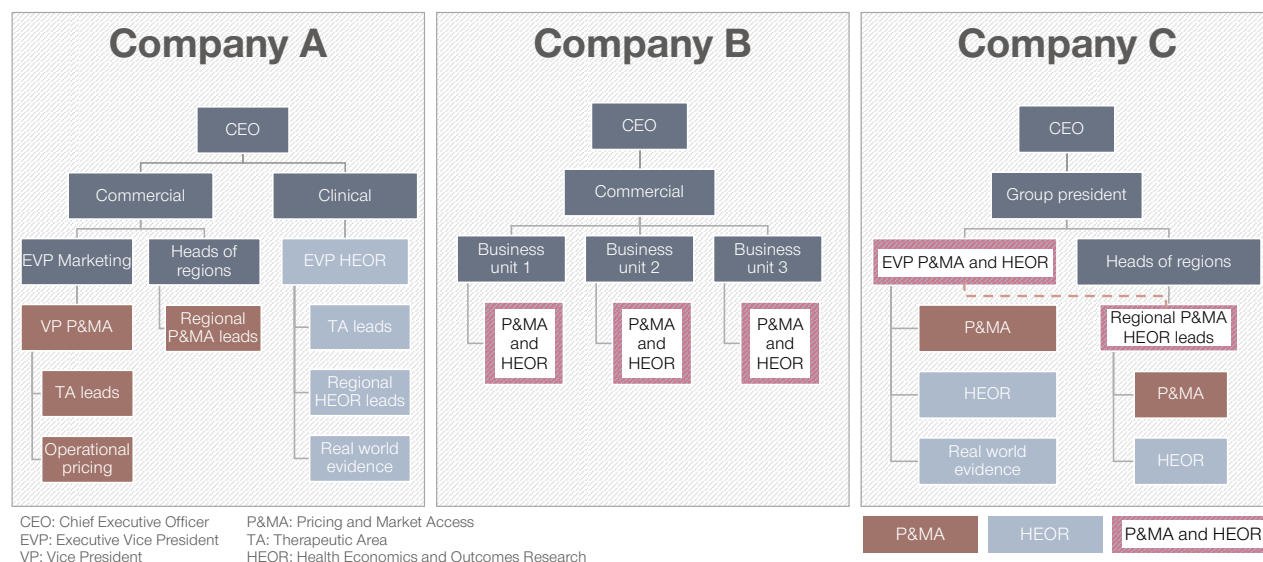
“When?” and “How?” deal with approaches and processes that support efficient task execution. Consistent approaches to all activities warrant reliable, high-quality P&MA input throughout a drug’s lifecycle while specific how-to-guides and templates ensure that materials are no longer highly variable. A systematic use of customized tools can also be helpful in this endeavour.

Roles and responsibilities

“Who?” relates to a transparent assignment of roles and responsibilities to support effective task execution and decision-making. It should be determined which parties are responsible, accountable, consulted, and informed (RACI) for each activity. Furthermore, the clear definition of the P&MA function’s role in key committees is advisable in order to create cross-functional touch points and support function visibility, e. g., by ensuring that P&MA has a seat in all key clinical development and brand strategy committees.

Since Germany is an example for a country with a relatively wide range of P&MA topics, it is crucial that the representative of the German P&MA team in the brand strategy committee is able to speak to all P&MA topics which might be relevant for a given product at a given point in its lifecycle. In theory, this can be achieved by appointing different P&MA professionals depending on the stage in the lifecycle, assuming that the P&MA focus tends to shift from dossier development towards price negotiations with GKV-SV and hospital/regional payer contracting. In practice, a variety of

■ Figure 2



Organizational set-up: P&MA on the global and regional level.

P&MA topics can be relevant at any point in time. Therefore, best-in-class companies nominate P&MA professionals who have the required breadth of experience and business sense for this role. These companies also articulate the requirements for this important role in a job description.

All in all, summarizing the scope of P&MA activities, processes, as well as roles and responsibilities in a tailor-made P&MA framework is widely regarded as a success factor for P&MA. Such a framework sets specific expectations, establishes accountability for key activities, and fosters internal alignment. It encourages cross-functional collaboration to guarantee that the P&MA perspective is considered throughout a drug's lifecycle, starting in early clinical development. To facilitate smooth onboarding and consistency in task execution, key P&MA activities can also be described in a detailed P&MA handbook.

■ Pricing governance

When it comes to operational effectiveness, one topic of particular importance is pricing governance. Pricing governance is about systemati-

cally managing prices and establishing a framework to enable this price management – particularly to steer, implement, monitor, and report on pricing. Smart pricing governance allows for effective and efficient price control as it balances flexibility for business optimization with safeguarding target and floor prices. It aims at capturing a drug's full price potential without stifling business opportunities or overwhelming the organization with internal price approvals. Consequently, escalation processes for price decisions are clearly defined.

Three types of price approval workflows can be differentiated: pricing strategies, launch price requests, and price change requests. It is important that list and net prices are both subject to pricing governance, since list prices impact international price referencing and net prices impact profit. Another success factor is the increase of governance scrutiny with the commercial importance of each brand. The tiering of products, e.g., based on lifecycle stage and/or annual revenue, can be key in this context. This approach follows the principle of optimal pricing governance which is

to decentralize where possible and require only senior management approvals when needed to maintain optimal prices.

Depending on the product portfolio, additional aspects need to be considered for developing optimal pricing governance. For example, biosimilars require a more pro-active approach and frequent reviews as well as adjustments of price targets and floors as this business is characterized by shorter negotiation cycles and the risk of a low-priced commodity market.

Talent management

The third pillar of P&MA Excellence is talent management. Successful P&MA professionals possess a combination of P&MA expertise, a good business sense and strong communication skills.

On the one hand, specific P&MA expertise is a prerequisite for developing optimal P&MA strategies. In German affiliates, profound knowledge of IQWiG and G-BA requirements as well as processes (e.g., G-BA early advice, G-BA hearing procedure, etc.) is essential for success-

ful dossier development. Moreover, in-depth expertise regarding the AMNOG process is of paramount importance for P&MA teams to understand the possible levers for a specific product. Best-in-class companies also ensure that P&MA professionals negotiating with the GKV-SV possess strong negotiation skills and are aware of the specifics of these negotiations compared to other types of negotiations (e.g., the negotiation partner is in a “monopolistic situation” and acting within a formal framework of regulations specifically set up for drug price negotiations in Germany).

On the other hand, a good business sense and strong communication skills are required for establishing successful relationships with payer customers and with stakeholders across the organization (e.g., with Commercial/Marketing, Clinical/Medical, Governmental Affairs, Finance). These working relationships provide the basis for productive cross-functional collaboration.

■ Competencies

Most successful P&MA functions detail necessary competencies by role and level (e.g., entry, mid-management, and leadership) to establish clear expectations for all P&MA professionals. The creation of role profiles can help to define core responsibilities, skills, and expertise. In this context, it is important to regularly assess required skills and competencies because they might

evolve as the company and the market environment change.

■ Progression

Second, it is advisable to design career progression paths so that professionals regard P&MA as an attractive function for career development. Career progression paths illustrate options of what prototypical careers could look like in terms of sequential positions, roles, and stages. Such a path illustrates career opportunities within the P&MA function as well as opportunities to switch across functions including temporary job rotations. Since pricing and market access are critical drivers of future success, C-level executives need to be familiar with these topics. Ideally, this is reflected in respective career paths which are developed in cooperation with the Human Resources department. As a result, P&MA becomes a stepping stone to upper management positions as it has been the case with other functions in the past.

At the same time, companies need to rely on a certain level of continuity and a backbone of expertise for which a retention program can be supportive. Furthermore, a succession management plan ensures the maintenance of the function's performance in case important P&MA professionals leave.

■ Development

Finally, it is recommended to invest in proper training and skill development to achieve continuous skill

growth in the P&MA function and to ensure that all P&MA professionals possess the required skills for their current role. This can be implemented in a comprehensive “Pricing and Market Access Academy” which is regularly updated to prepare P&MA professionals for future challenges and opportunities.

Conclusion

The P&MA function plays a critical role throughout a drug's lifecycle as it lays the foundation for patient access and commercial success. Consequently, optimizing the organization and operations of the P&MA function is a priority for any company looking to succeed in a challenging payer environment. To achieve continued P&MA Excellence, successful companies ensure that P&MA is a central and integrated part of the organization which is reflected in its organizational set-up, operations, and talent management.

Correspondence:

Stephan Schurz
Simon-Kucher & Partners
Willy-Brandt-Allee 13
53113 Bonn (Germany)
e-mail:
stephan.schurz@simon-kucher.com