

Drug pricing and market access: why is it so hard to get all the pieces working together?

The market access function is quickly evolving. Defining its roles may imply invading professional territories claimed by other functions, say *Josée Hulshof* and *Jens Müller*.

The recognition by pharmaceutical companies that product development and marketing strategies must consider payer requirements to obtain acceptable levels of price and reimbursement comes with organisational challenges spanning from headquarters to country offices and field functions.

It is now common practice that HQ-based pricing and marketing access (P&MA) – including or supported by health outcomes – provides country teams with a core value dossier, core value messages and core health economics models for each product close to launch. The respective processes also tend to be well established.

It gets more complex earlier in R&D (prior to Phase III) where P&MA's role is perceived as underdeveloped and under-resourced. In Phase I and II cross-functional teams, the voice of P&MA is often overruled by clinical research. The goal that trumps all others is typically to get the new product approved by the regulatory authorities as soon as possible and to accomplish this within the allotted research budget. The consequence could be that the choice of clinical comparator may not support the target price; the follow-up time may be too short or end-points not accepted for positive reimbursement decisions. Recently, companies have learned the hard way – from hampered market uptake due to lack of convincing payer evidence to unfavourable pricing decisions in key markets. The belief that payer considerations are too diverse and not an investment priority is now disputed with increasing success by P&MA staff in cross-functional product development teams.

Yet there is still a long way to go to balance the different stakeholder requirements in clinical and marketing decisions and to optimise product development investments between regulatory and price/reimbursement approvals. P&MA joins the cross-functional team mostly at a later point in time, when some irreversible decisions may already have been made. Investing too much too early is not a wise solution either given the high attrition rate. Well-described procedures for balanced decision-making and escalation routes are needed to sort through diverging views.

P&MA departments in country offices tend to feel thinly spread over many tasks. Their core task is to “win with payers” through preparing dossiers, conducting payer negotiations and supporting the payer field staff. However, they

also need to align with marketing on product strategy, with regulatory affairs on optimal “label language” and with HQs on future payer requirements (comparator, trial design and duration, health economics requirements) for pipeline products.

They must also digest product information from Phase III trials, anticipate the impact of competitor entry on price or reimbursement positioning and stay abreast of policy changes. Most P&MA teams would agree that the broad range of responsibilities is an intrinsic part of their role. However, they would also confess to focusing on products in launch phase and then struggling for time to maximise opportunities for products later in the life cycle and earlier in the pipeline. They feel squeezed between demands of local product teams, field requests and HQ expectations.

Such unclear and conflicting priorities often become apparent when working with affiliates. This is particularly true in countries where payer scrutiny focuses on clinical value substantiated by local evidence. This demands sophisticated P&MA input from Phase I or II onward to ensure payer-inclusive trial design of both the global and local trials and is a condition for premium price. Designated competent staff and clear processes must be in place to get this work done.

In the field, P&MA (payer field force, payer key account managers) shares the space with sales representatives and medical liaisons, potentially calling on the same customer and struggling to define “ownership” and to align messages. Most companies understand that payer clients and hospital procurement have different needs from prescribers. Payers are more complex, have mostly a longer time horizon and their decisions affect larger populations and take longer. P&MA has to balance clinical and economic value messages, must cover a portfolio of products, and manage sophisticated advisory committees. Re-designing the payer field role may contribute tremendously to improved net prices and broadened market access. One often hears that the P&MA field force feels that job descriptions and performance metrics do not reflect its work. Greater clarity on job expectations, deliverables, goals and targets, and fitting performance metrics allow the team to “right-size” and achieve improved results.

Market access is a fairly new function, with many cross-functional linkages. Its roles and

responsibilities are often ambiguous and defining them may imply invading other professional territories. Mature functions such as marketing and sales, clinical research and regulatory have their key processes and touch points with other functions described in standard operating procedures, yet P&MA deliverables are rarely included.

With the lack of role clarity, it is unsurprising if a competency gap for P&MA staff exists. P&MA staff in HQs and large country offices are often weak in clinical research and regulatory requirements, which undermines their strength of argument in the R&D arena. In the field, key account management and negotiation skills are often insufficient. Given the relative novelty of the function, its fast expansion and high turnover rates, optimising performance of P&MA staff is a challenge. It is even harder to gain understanding of P&MA needs among marketers and clinical researchers.

Three lines of effort will contribute to get all the pieces working together:

- Enhance effectiveness of cross-functional teams in product development by requiring clinical and regulatory staff to gain deeper knowledge about pricing and market access, and P&MA staff about clinical trials and regulatory requirements.
- Clarify the roles of P&MA staff and identify corresponding required skills levels. A tailored competency development programme can then be designed and rolled out.
- Document the most important internal deliverables and corresponding timelines to ensure timely input about payer requirements and proper representation of the payer perspective. Translate these where needed into SOPs and performance metrics that reward the right results and behaviours. Implementing the above is much easier if the P&MA function has strong, unequivocal leadership, anchored high enough in the hierarchy to drive change where needed. However, it remains to be seen whether strong P&MA leadership is the start or the consequence of the increasing maturity of the P&MA function.

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