FEATURE

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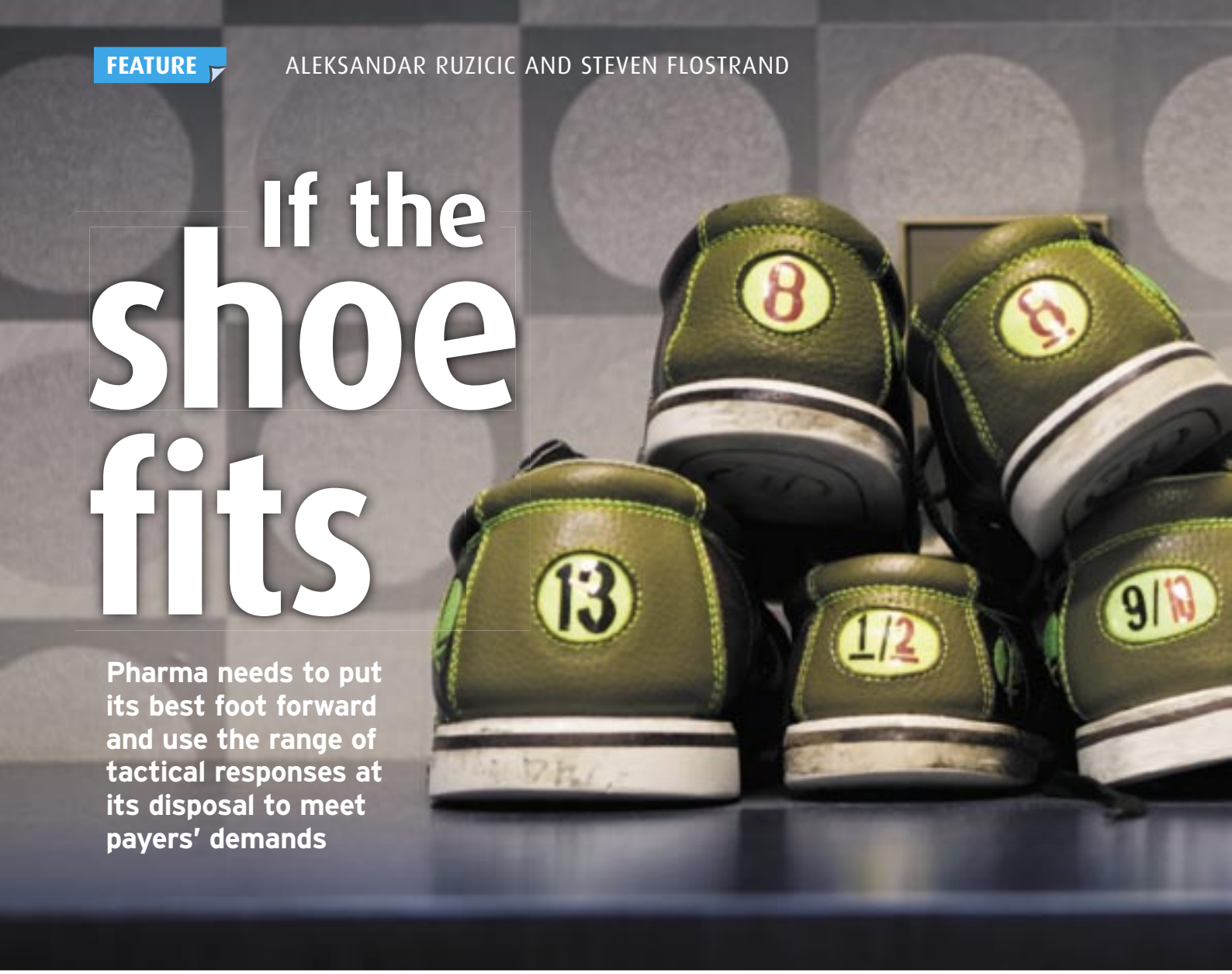
If the shoe fits



Pharma needs to put its best foot forward and use the range of tactical responses at its disposal to meet payers' demands

Despite what we are asked to believe, pharmaceutical marketers used to have it easy. Marketing predominantly to doctors, companies positioned their patent-protected drug against competitive products, seeking any meaningful differentiation to drive market share (or occasionally market growth). "Price" was exogenous to the marketing mix; constantly increasing in the US, constantly declining in most of the rest of the world. However, soaring healthcare costs have resulted in governments, health services and payers taking an active role to curb this unsustainable trend. These new customers have significant power and in past years have redefined the value of pharmaceutical products. What's out: innovation. What's in: outcomes.

GOLD STANDARDS

It is no longer sufficient to have a patented active ingredient; companies need to demonstrate value in everyday situations with real patients against established "gold standards". And many of these gold standards will soon go off patent, with more than $100bn of drugs losing protection by 2012. To survive, pharmaceutical companies need to revalue their offering and adapt their business model, commercial approach and pricing strategies, or face fierce competition from generics.

Two major dimensions drive the value of pharmaceutical offerings. The first relates to product uniqueness and this is the pharmaceutical marketer's traditional ground. In the past, all patent-protected products were regarded as innovative (and therefore unique), including first-in-class active ingredients and me-too products. Now, payers reject this positioning, particularly in crowded therapeutic classes where generics exist. Recently, Merck & Co and Schering-Plough failed to convince payers in Italy and the UK of the uniqueness of their combination product ezetimide and simvastatin (which was already off-patent).

If uniqueness is less valued by payers, other stakeholders more sensitive to this claim will have to be targeted. Depending on the country and/or indication, companies may have to target patients. Consumers are particularly important in emerging markets, which will contribute more than half of the absolute growth in the coming years due to large out-of-pocket payments. As shown for OTC brands in the Western markets, it can be lucrative to build strong brands in the OTX area, particularly since spending power is (still) limited, driving

the need for affordable products with proper formulation or packaging rather than superior outcomes. GlaxoSmithKline and sanofi-aventis are committed to the emerging markets, as evidenced through numerous acquisitions since 2008.

To build value through uniqueness among payers, the critical factor will be the superiority of the clinical profile compared to existing products on the market, particularly the gold standard. Of course, a superior clinical profile can be achieved even for off-patent active ingredients, for example through a new indication, such as thalidomide against multiple myeloma or novel drug delivery mechanisms, such as demonstrated by Ciba-Geigy/Novartis through a variety of formulations for the active ingredient diclofenac (Voltaren tablets, gels, drops etc).

The second dimension relates to the ability to compete on outcomes. Ideally, the clinical profile of unique products should translate into superior outcomes, but this is not a given. Good examples are drugs to treat rare diseases where no alternative exists. Yet even breakthrough medicines will have to stratify patients to compete on outcomes measured using cost-effectiveness analysis. Roche/Genentech has adopted the strategy first with Herceptin, targeted at breast cancer patients depending on the level of expression of the receptor tyrosine kinase HER2/neu. Were sanofi-aventis to launch Plavix today, the cytochrome P450 2C19 (CYP2C19) test would most certainly be used to exclude non-responders and drive better outcomes.

OUTCOMES

Still, for most chronic diseases, it is difficult to compete on outcomes. Lifestyle, environment and the healthcare professional treatment typically contribute more to the outcome than the drug. The pharmaceutical industry has offered compliance and disease management programmes in these areas as part of their marketing and sales efforts, by adding services around their products. Faced with payer demands, these offerings will have to evolve into integrated and monitored healthcare solutions. A trigger point will be the willingness of payers to agree upon full treatment costs for specific conditions, encompassing all products and healthcare services related to it as postulated by Professor Elisabeth Teisberg. For diabetes, asthma and cardiovascular risk management, one could imagine annual treatment costs per patient with a bonus/malus depending on the achieved outcome/quality of care, eg, percentage of hospitalisations per treated patient year.

If a pharmaceutical offering cannot be uniquely positioned at the product level, nor compete successfully on outcomes, it will fall into the final, most price-sensitive category, together with generics. Creation of value will be at a commercial level offering, perhaps, superior services to pharmacists, typically driving volumes rather than premiums. The pressure on non-differentiated drugs, particularly after first-in-class generics hit a category, will increase tremendously through mechanisms such as reference pricing with "jumbo" groups, payer contracting deals and generic tenders, all of which have been applied in Germany, for example. Given soaring healthcare costs, most countries will impose drastic price containment mechanisms. Undifferentiated products – willingly or not – will join the slide to the bottom.

PROFOUND DIFFERENCES

The message for marketers is clear: in the future, differentiation will be about more than an active ingredient with a good safety and efficacy profile. The four categories identified have unique key success factors, require tailored commercial core competencies and follow optimised pricing strategies.

The traditional pharmaceutical market for innovative products will remain highly lucrative for marketers who can demonstrate a superior outcome for a specific patient (sub-)population. Marketers will need to pick the proper target groups carefully to ensure adequate clinical information for their cost-benefit assessments. Otherwise, they will not only jeopardise their premium pricing, but also their competitiveness at large. As shown in countries like England, a failure to produce relevant evidence for a cost-effectiveness assessment will not result in lower prices, but outright reimbursement denial. Examples for the superior outcome strategy are orphan drugs and selected first-in-class therapies, with novel mechanisms of action delivering breakthrough outcomes.

Marketers have long experience with customer loyalty strategies, both with patients and physicians. Faced with limited reimbursement for conditions such as hair loss and erectile dysfunction, companies have built brands based on strong customer understanding. In addition to branding, pharmaceutical marketers made patients aware of the condition and ensured that they asked their doctors for the required prescription. In return, these products command a premium driven by brand loyalty, particularly for products paid for fully out-of-

Table: Positioning and Competition of Different Strategies

	Is There Competition on Outcomes?	
Is the Positioning Unique?	**No**	**Yes**
Unique	**The customer loyalty strategy** **Key success factor:** Loyalty through brands and/or relationships **Commercial core competency:** Customer understanding and brand management **Pricing strategy:** Premium based on brand loyalty, either from consumers or physicians **Examples:** OTC and OTX, such as erectile dysfunction	**The superior outcome strategy** **Key success factor:** Superior outcome for a specific patient (sub-)population **Commercial core competency:** Cost-benefit assessments for reimbursement **Pricing strategy:** Premium, justified by outcomes and sustained by uniqueness **Examples:** Orphan drugs, some first-in-class therapies
Not unique	**The commodity strategy** **Key success factor:** Product/services bundles **Commercial core competency:** Distribution channel and/or category management (across a TA) **Pricing strategy:** Low-cost, contracting, commercial service agreements (such as up-selling courses, paid-for services) **Examples:** Generics and me-toos (after first-in-class generics)	**The healthcare solutions strategy** **Key success factor:** Comprehensive healthcare solutions, eg compliance programmes, disease management **Commercial core competency:** Payer/provider partnerships (set-up, execution, results tracking) **Pricing strategy:** Fixed-fee/capitation for a condition, pay-for-performance/risk-sharing schemes **Examples:** Takeda UK Cardiology, Pfizer Health Solutions

pocket by the patients. Similarly, marketers have built multi-billion dollar businesses by switching brands from Rx to OTC towards the end of the patent-protected period, in categories such as allergy and gastrointestinal drugs, a trend further promoted by governments trying to curb their healthcare bills.

The healthcare solutions strategy is a more risky, but potentially highly rewarding, alternative in the long term. Building on comprehensive healthcare solutions with a measurable outcome improvement, such as compliance programmes and disease management, marketers can strike partnerships with payers/providers.

Today, they have to master the set-up, execution and results tracking of these partnerships, supported by relevant tools such as call centres and e-health solutions. Tomorrow, they will have to align their pricing strategies, for example through fixed-fee/capitation for a condition and pay-for-performance/risk sharing schemes. In the absence of therapy advances, they may secure a continuous revenue stream around their products. However, few companies have shown much willingness to take this step and pharmaceutical companies may find themselves out-competed by specialist health service companies that are already emerging, such as Fresenius Medical Care and Euromedic for end-stage renal disease patients requiring dialysis.

Companies without a superior outcome claim or unique positioning will take their lessons from today's commodity suppliers; oil companies learned long ago that the real value of the petrol station lay not in the forecourt, but in the always-open convenience store where the consumer could find milk, eggs, cigarettes, newspapers and so forth – for a premium price. However, this will require product/services bundles for the distribution channels, combined with strong category management across a therapeutic area.

MARKETING IMPLICATIONS

More demanding and heterogeneous customers will require changes to the marketing organisation, beyond merely adding "market access" to the title of current product managers. The above strategic choices are not entirely exclusive and companies must work to demonstrate outcomes upstream during development and be ready to 'fight it out' later on. This does not mean adopting the current "risk-sharing" approach to achieving market access. It is our view that such schemes are a consequence of inadequate upstream preparation of the value story. If not resisted, these schemes will quickly become the norm, limiting both uniqueness and outcome differentiation.

Avoiding the commodity strategy requires significant investment, made early and sustained over time. These investment decisions cannot be made by global marketing in isolation, as the market conditions and payer needs will be crucial inputs to the creation of a superior outcome strategy. Increasingly, companies investigate payer needs during phase II of the development programme. We predict that this analysis will move completely to the start of the development process, modifying the "what is the unmet need?" question to a more nuanced "what is the improved outcome that payers seek and how much are they willing to pay for it?" Of course, payers have no monopoly on identifying medical demand and companies will need to market their development plans to payers at this early stage, to convince them that improving a given outcome is both in their interest and within their means.

From a global versus local split of responsibilities (strategic versus operational), upstream and downstream marketers will emerge; these will be required both at headquarters and in-country. As mentioned, upstream marketers will develop new capabilities to identify, communicate and realise opportunities to achieve superior outcomes across key markets, while downstream marketers will take the products and channel them into markets where they can either be unique or deliver superior outcomes.

Product management will remain important, particularly when companies pursue a customer loyalty strategy. The customer target group will shift and expand, however, as doctor decision power declines and consumer power continues to rise. On the other side of the strategic field, pursuing the healthcare solutions strategy will require real therapy management competency. As payers themselves evolve towards a type of category management (managing categories of health outcomes by sourcing different drugs, interventions and care levels from multiple suppliers), companies will need to reinforce their category expertise at both levels and key account management skills downstream. The choice of whether to build or partner to deliver the outcomes demanded will be of great importance and is likely to be the key local strategic decision.

Finally, companies that pursue a commodity strategy by choice or necessity will find that today's "mature" and "heritage" marketers will grow in importance. Their portfolios will expand and the receptiveness of payers and the distribution chain to their commercial offerings will increase. The shift from selling pills to doctors to delivering outcomes to payers has just begun. From an initial defensive reaction, the industry now has a range of tactical responses to payer demands and we have seen an explosion in the recruitment of a new marketing breed – the pricing and market access manager. As the full strategic consequences become visible, these new marketing managers will be found increasingly on R&D teams, country management boards and, at some point, the executive committee.

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