

VALUE-CREATION OPPORTUNITIES FROM MARKET DISCONTINUITIES IN THE PHARMACEUTICAL INDUSTRY

Avoiding value-destruction from patent expiry in a branded therapy market

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Abstract

Patent expiries within a therapy class pose an especially complicated challenge for branded pharmaceuticals. This requires the remaining branded players to justify their price premium to maintain physicians' usage as the generic drug becomes available, or to reconsider their premium pricing position by evaluating the value-creation of alternative strategies. This paper outlines an approach for dealing constructively with this challenge based on the coordinated application of market intelligence and business strategy simulation modelling for the development of robust value-retaining strategies. Insights developed from recent client work suggest it is a reliable methodology for evaluating patent expiry challenges in the pharmaceutical industry, enabling significant value-creation. The discussion furthermore suggests key benefits may be achieved from applying strategy dynamics and system dynamics based approaches, to derive strategic direction in market discontinuities.

Keywords

Strategy dynamics, Pharmaceutical marketing, Brand management, Patent expiry, Strategy simulation, Integrated intelligence, Scenario modelling, Value-creation.

VALUE-CREATION OPPORTUNITIES FROM MARKET DISCONTINUITIES IN THE PHARMACEUTICAL INDUSTRY

Avoiding value-destruction from patent expiry in a branded therapy market

Patent expiries are becoming increasingly important challenges for the pharmaceutical industry. With the falling numbers of new drugs being launched, and R&D expenditure nearly doubling every five years¹, retaining value-creation from existing brands in the face of patent expiries is increasingly important.

When a patent expires, generic manufacturers are able to copy a product and sell it at a discount, often a 70% price reduction. There are two types of patent expiry challenges in this context: firstly for the patent owner – for whom a patent extension strategy must be devised to minimise generic substitution, and secondly for the prevailing branded drug owners in the class.

This latter group has to re-assess the sustainability of their present strategies and consequently make tough decisions on how best to compete for choice² in the face of new generic substitutes.

The problem is that value is often destroyed in this context as brand owners are unable to make the appropriate judgements in deciding whether to continue to compete for choice by supporting the brand in justifying their premium price, and then to make the right allocation of resources required.

This paper introduces a methodology to address these two challenges in developing strategic insights on the opportunities and requirements for sustained value-creation from a patent expiry³.

THE CHALLENGE – CONTINUING TO JUSTIFY THE PRICE PREMIUM

Value-destruction is often a threat to all brands remaining in a class as patents expire on a particular product and generics become available. The availability of cheap generics puts pressure on the remaining brands to justify a premium price. In response to this challenge, pharmaceuticals often decide to ‘milk’ the brand by

¹ Number of drugs approved in the US down to 24 in 2001 from a high of over 50 in 1995, and R&D spend up from \$17bn in 1995 to more than \$30bn in 2001 – [New Herald Tribune](#), April 20-21, 2002

² Finskud, L., Desmet, D., Glucksman, M., Marshall, N., Reyner, M. & Warren, K. (1998). The end of voodoo brand management. [McKinsey Quarterly](#), 2.

³ This paper is based on a recent client example. All material has been disguised to protect client confidentiality.

slowly reducing price and removing support, even though the health of the brand resources⁴ could sustain choice at a premium price position.

There is an alternative to value-destruction

In these cases, a decision to justify a price premium for the brand and continue to compete for choice can enable the brand to retain breadth of use and depth of prescribing⁵ at a premium price position. This translates to value-creation for patients, physicians and the brand owner, well beyond what can be achieved from a 'milking' strategy.

In justifying the price premium, however, brand managers must ensure that their brands provide sufficient benefits to physicians and patients for continued prescribing in favour of low cost generic substitutes.

All too often, however, this is complicated by a lack of relevant intelligence to evaluate the appropriateness of alternative strategies. Intelligence is required on the relative health of current brand resources and the ability to develop, provide and promote superior tangible and intangible benefits to key stakeholders in response to the patent expiry impact.

The health of brand resources determines whether your brand can continue to justify a price premium

Where the brand resources are healthy, value-retention strategies which build on justifying a premium price can be successfully developed. However, this demands a detailed understanding of the brand, the competition and the expected strategy dynamics⁶ in the market.

In a client case, the initial brand analysis looked promising (see Exhibit 1). Growth of the brand had been strong based on a positioning of cost effectiveness promoted by a higher efficacy and lower price message, and it had recently overtaken the 'market leader' in terms of new treatments. The brand had furthermore attracted a net gain of users switching from the 'market leader'.

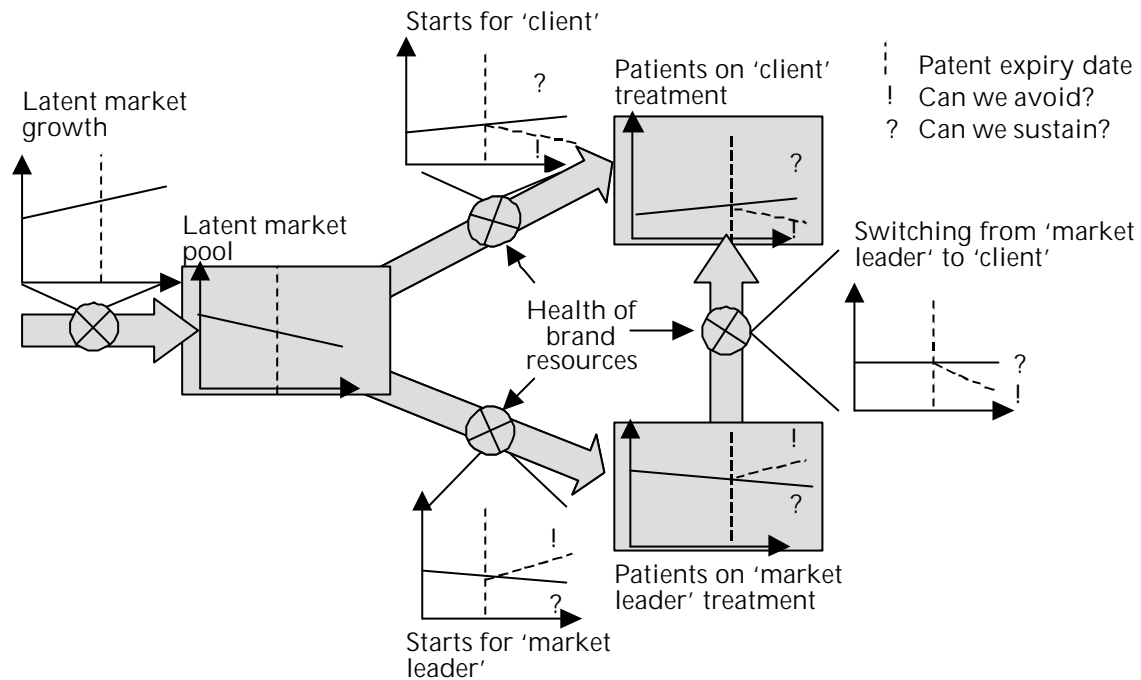
In addition, market growth was expected to continue to be high, fuelled by increased incidence rates and by a continued switching of patients treated with less efficacious drug classes.

⁴ 'Health of brand resources' is a term defined as the relative resource position of the brand and the potential ability of the brand to extract value from stakeholder choice. Resources in this context are the totality of resources available to the brand, including for example the stock of physicians perceiving the brand as high quality.

⁵ 'Breadth' of use is defined as the share of the number of physicians prescribing, and 'depth' of prescribing as the share of scripts across appropriate indications of those who do prescribe the brand.

⁶ Warren. K. (2002) Competitive Strategy Dynamics, Global Strategy Dynamics, in press

Exhibit 1. Simplified illustration of the brand rivalry and the role of the health of brand resources



While there was an appreciation of opportunities to retain value-creation from the brand, the trends that had looked so promising were now facing a discontinuity that could potentially reverse them. This could possibly lead to an increasing share for the generic version of the 'market leader', and a halt to, or even reversal, of the flow of switching that our client's brand had been attracting.

The impending patent expiry of the leading brand would create an environment where a positioning based on price would not be sustainable, requiring a decision to either reposition or to remove brand support and 'milk' the current prescriber base.

In addition, local healthcare initiatives to manage budgets were leading to increased price sensitivity of prescribing in both primary care (the community/GPs) and secondary care (hospitals/specialists), making premium pricing increasingly challenging.

Determining the right response based on analysis of health of brand resources and the ability to respond to the impact of the patent expiry

In this context brand owners must determine the resource requirements for continuing to justify the premium price by ensuring good relative health of brand resources given the patent expiry impact. The brand owner must furthermore determine the relative importance of the brand in the portfolio to evaluate if the resources can be more profitably allocated to other brands.

This analysis will be dominated by the relative impact of the patent expiry on the class and its impact on the relative health of the brand's resources. Consequently, as

a starting point in identifying the right choice of strategy, we propose to assess the appropriate response to a patent discontinuity by evaluating the options in a classic two-by-two strategy matrix. See Exhibit 2.

Exhibit 2. Responding to in-class patent expiry – Strategic options

Impact of patent expiry on the business environment	High	<p>Manage for cash to extract maximum value</p> <ul style="list-style-type: none"> • Reallocate resources to other brands • Cut costs, and discontinue 	<p>Invest in premium brand value positioning</p> <ul style="list-style-type: none"> • Position with value added services • Minimize impact of expiry
	Low	<p>Rebuild, or sell to reallocate resources to other brand</p> <ul style="list-style-type: none"> • Rebuild brand to enhance value • Reallocate resources 	<p>Leverage core resources for value-creation</p> <ul style="list-style-type: none"> • Continue strategy as is • Optimise sales and marketing
		Poor	Good
Relative health of brand resources at patent expiry			

In a high impact scenario, for example, when the patent expires for a ‘market leader’ drug, the pressure on the remaining brands to lower price will increase as the drug price of the ‘market leader’ falls. As price pressures increase, the positioning and health of brand resources of some brands become unsustainable.

The appropriate response to a patent expiry in this context will depend on the relative health of a brand’s resources given the impact of the patent expiry. If the health of the brand’s resources is good, despite the impact of the patent expiry, the appropriate response is to develop a compelling value-proposition that justifies a premium price, leveraging these brand resources. See the top right corner in Exhibit 2 above.

Consequently, brand owners need to evaluate the health of current brand resources, the opportunities from alternative, their requirements, and whether the company has the ability to fulfil these requirements. However, this is typically complicated by a product focus, and an associated poor intelligence base for understanding the opportunities for value-creation for the stakeholders involved in the therapeutic process.

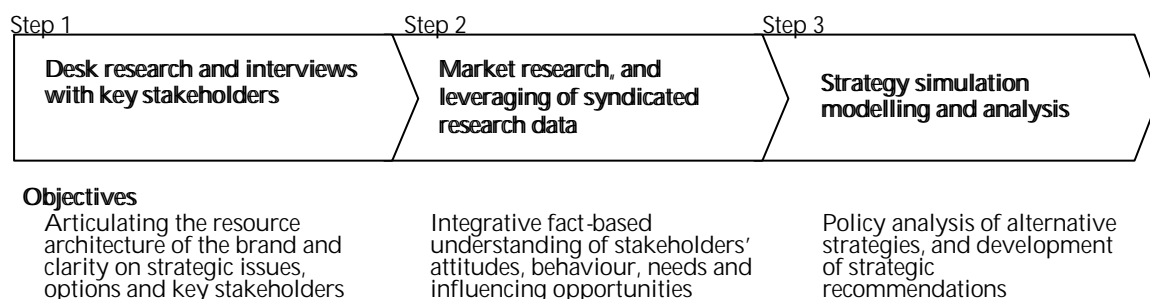
APPLYING INTEGRATIVE INTELLIGENCE AND SIMULATION MODELLING TO EVALUATE STRATEGIC OPTIONS

To resolve the challenges in this particular case and avoid premature price-cuts, withdrawal of crucial promotional or value-added support, and/or too optimistic repositioning efforts, a reliable intelligence base and a structured understanding of the ability to sustain the relative health of the brands resources was developed.

Whilst all client situations require customized work, Vanguard has developed an approach leveraging the benefits associated with its system dynamics modelling and branding expertise from the consumer industries, as well as an intimate understanding of the intelligence available in the pharmaceutical market.

This approach was applied, focussing on three steps: developing clarity on strategic issues, commissioning of new intelligence, and developing a detailed dynamic simulation model to evaluate alternative strategies. See Exhibit 3, below.⁷

Exhibit 3. Outline of process for developing dynamically informed strategy



Each of these was sub-divided into coordinated key analysis and development steps. These are outlined in detail in the following sections.

Step 1 – Articulating strategic issues and resource architecture through desk research and stakeholder interviews

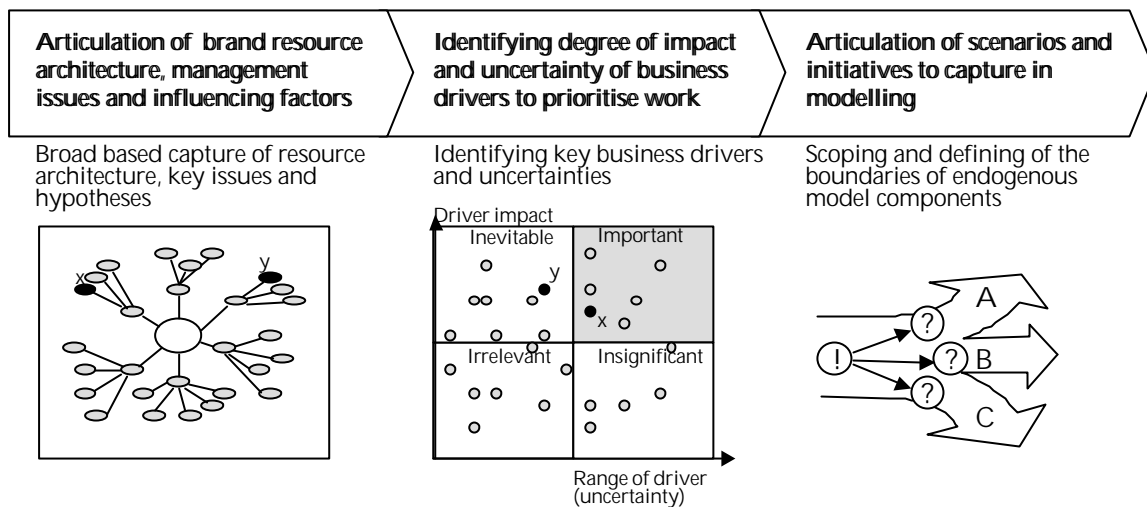
The first step was to develop clarity on strategic issues such as strategic options and the relative importance of key stakeholders (patients, nurses, primary and secondary care physicians, primary care organisations and trusts (PCO/PCT⁸), and regulatory bodies (NICE⁹ etc.). This process leveraged management interviews, workshops, and market and business intelligence to achieve a basis for developing required new intelligence and for determining the right scope of the strategy simulation model. Exhibit 4, provides an illustration of this process.

⁷ The project ran over a three-month period, including the time to turn around the market research initiatives and analyse the results.

⁸ Primary care organisations in the UK come under a variety of names depending on regions; here 'organisations and trust' is used as a common term for all the institutions that serve to coordinate public healthcare at the local level.

⁹ National Institute for Clinical Excellence, a UK government body designed to evaluate alternative therapies and provide guidelines for best clinical practices.

Exhibit 4. Development process for scoping and articulation of analysis and modelling requirements



The specific activities in this process included:

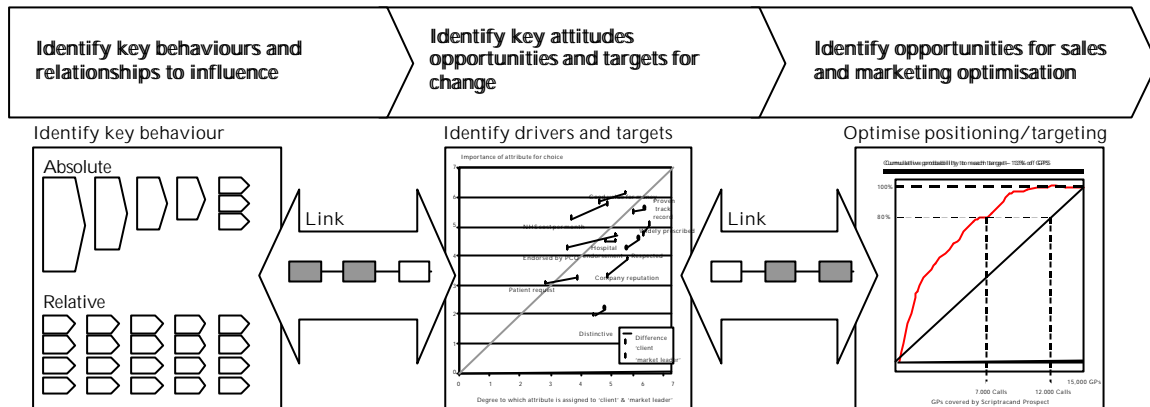
- ◆ Management interviews supported by detailed market performance analysis based on desk research of available internal and external intelligence sources
- ◆ A scenario driver analysis workshop to identify the boundaries and key issues to capture in intelligence and modelling
- ◆ Integration of analysis from qualitative and quantitative research to generate market scenarios and pertinent strategic and tactical initiatives to help identify the right solutions.

Step 2 – Developing fact-based integrative understanding of key stakeholders through market research and leveraging of syndicated research data

The second step was to develop an integrative understanding of stakeholders' attitudes, behaviour and needs, including influencing factors and opportunities. As intelligence covering the stakeholder choice process nor the resource architecture of brands was available, new intelligence was commissioned. New quantitative market research and syndicated research databases through *ad hoc* queries was developed for each of the key stakeholders.

This second process builds on the insights developed from the analysis and modelling activity described in Exhibit 4 and is used to populate the simulation model shown in Exhibit 6. Exhibit 5 describes this process for establishing actionable analysis and insights.

Exhibit 5. Development process for establishing integrative intelligence enabling actionable segmentation and profiling of key stakeholder segments



Intelligence was designed to identify key stakeholders based on three key characteristics: behaviour, attitudes (including perceived needs and values associated with the class), and relative influences of other stakeholders and media channels. This was developed in two components:

Firstly, linked data for the three areas was developed to ensure the right basis for actionable segmentation and profiling of the key stakeholder populations:

- ◆ Reliable behaviour information based on *ad hoc* queries to behavioural data-bases for the key stakeholder populations – e.g., primary care prescribing leads, general practice physicians, self-medicating general population, treated sufferers, and patients currently being treated with a drug in the class concerned
- ◆ Key behaviours were captured through questions in *ad hoc* research for integrative data with links to attitudes and influencing opportunities for each of the key stakeholder populations
- ◆ Past prescribing behaviour of clusters of physicians on attitudes and sales and marketing exposure was linked (through third party integration of clustered data)¹⁰.

In the second component, this intelligence base was analysed to develop actionable insights into the following areas:

- ◆ Quantifying key stakeholder behaviours and comparative choice-pipeline performances
- ◆ Analysing key stakeholders' behaviours and attitudes to develop segmentation and profiling to direct design of alternative initiatives

¹⁰ Cross-linking of data sources including personal information about individual physicians prescribing behaviour is not allowed in the UK, requiring analysis based on clustering of physicians through third parties.

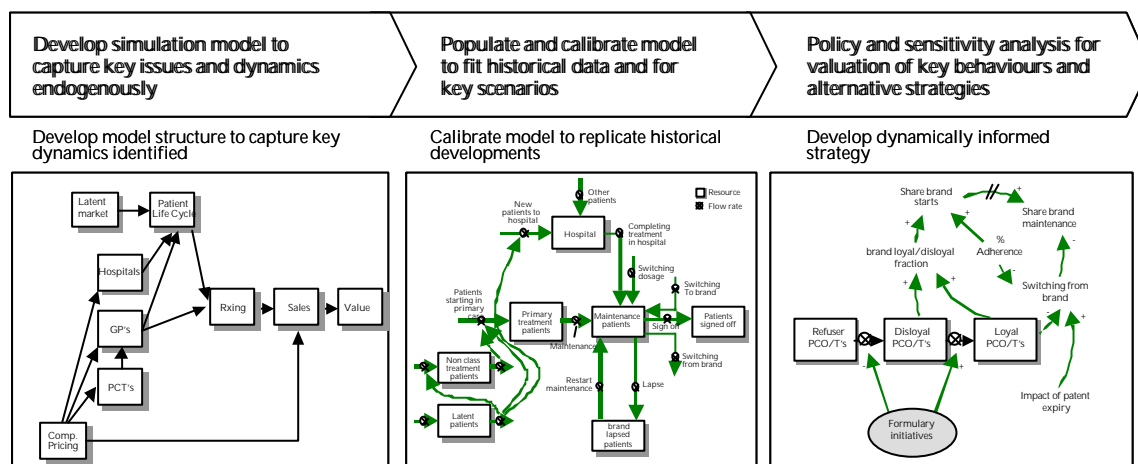
- ◆ Evaluating sales and marketing opportunities by linking initiatives to targeting predictions made from profiling data available through the ETMS (electronic territory management system) and stand-alone physician databases.

Step 3 – Developing dynamically informed strategy recommendations through strategy simulation modelling and analysis

The third key process component was the analysis of alternative strategies, including those which would justify a price premium, and determining the right timing and sequencing of initiatives to achieve maximum value-creation for all stakeholders under a range of plausible market development scenarios. This required the development of a strategy simulation model where key stakeholder initiatives were articulated and tested.

This model was designed to analyse driver sensitivities, strategic and tactical initiatives, and the appropriate timing and sequencing of these initiatives to yield business synergy, as shown in Exhibit 6.

Exhibit 6. Process for development of strategy simulation model for developing robust dynamically informed strategy (simplified)



This consisted of three main steps:

- ◆ Leveraging the insights developed from the management interviews, desk research and business driver workshop to determine the appropriate components, structure and boundaries of the model
- ◆ Populating and calibrating the model to fit historical data as a basis for developing key scenarios and implementing the structures relating to alternative policies

- ◆ Policy and sensitivity analysis to evaluate alternative strategies, and the requirements for success of these strategies under a range of market scenarios.

The simulation modelling approach undertaken was similar to a system dynamics project. However, it differed from a traditional approach in terms of the comprehensive intelligence development effort undergone in parallel with the model development.

The model was co-developed with the client to leverage the approach and facilitate the adoption of the resource-based view in the organisation.

THE BENEFITS ACHIEVED FROM THE ENGAGEMENT APPROACH

The application of system dynamics modelling, informed with market intelligence, provided a number of key benefits for the client:

- ◆ Enabled the formulation and shared understanding of real opportunities for value-creation for all stakeholders despite the patent expiry – allowing a significant upside over the expected lifetime of the brand to be captured for the UK market alone, relative to a worst-case scenario
- ◆ Created a shared brand architecture for the client management team to identify key dynamics and management levers to drive the stakeholder choice pipeline and the justification of a price premium
- ◆ Provided a model to extract maximum value from available intelligence sources; previously the client organisation had used intelligence sources in isolation without developing an integrated view
- ◆ Supported the development of integrative quantitative market research – the creation of a stock and flow representation of the business identified key data needs
- ◆ Developed actionable segmentation, clarifying the value-potential of stakeholder segments and how to realise this value
- ◆ Devised intelligence requirements for development of tactical and strategic initiatives, as well as for targeting and message optimisation
- ◆ Key performance indicators (KPIs) and lead indicators for decision-making were identified to facilitate contingency planning and sustain the shift in management focus toward the new blueprint for success.

CONCLUSIONS AND DISCUSSION

This structured approach has served as the basis for decisions leading to sustained value-creation and competitive advantage to client brands as well as for the other key stakeholders, including patients and the national health systems through the development of value-added services and patient support.

In summary, three key benefits were identified from applying the strategy dynamics approach and the system dynamics methodology:

- ◆ The approach provided a robust solution to determine the most value-creating strategy from a patent expiry by enabling a fact-based, long-term, and time-based view on how and where to compete
- ◆ The approach enabled a shared mental model of the brand architecture, a clear description of key strategic initiatives, and a clear focus on value-creation, overcoming communication challenges in translating the business insights to the managers who are required to implement them
- ◆ Finally, the approach enabled innovation in pharmaceutical strategy development by making system dynamics based scenario modelling appealing to senior managers. This was achieved by taking a brand and stakeholder-choice focus and integrating key market research to enable a high degree of confidence and dynamically informed insights within a very short time-horizon.

Although this paper focuses on the challenges associated with developing alternative strategies, and on choosing the most robust and dynamically informed strategy for patent expiry discontinuities, the methodology can be applied to other discontinuities.

Indeed the Vanguard approach has generated significant interest in the use of business simulation and integrated intelligence development for brand strategy improvements. The approach is currently being applied to a wider area of strategy development within the pharmaceutical industry.

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The author;

Fredrik Elg is a senior consultant with Vanguard Brand Management. He holds master degrees in Psychology and Business management, and a Ph.D Lic. in Cognitive engineering.