



PRACTITIONER PERSPECTIVE

“Pressure points” on pharmaceutical industry executives: what lies ahead?

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Abstract

Purpose – The pharmaceutical industry faces significant challenges in the immediate future, including drug safety, intellectual property in emerging markets, industry image, and the overall effect of marketing. To remain effective, pharmaceutical executives must translate these challenges to the industry into solutions, find relationships between individual issues, and group these issues into larger themes. The purpose of this paper is to study the issues that senior industry executives perceive the pharmaceutical industry faces and how they can organize these issues into high-impact “pressure points.”

Design/methodology/approach – Using a modified approach to the Delphi technique, 70 senior pharmaceutical industry executives rated issues facing the pharmaceutical industry. Their responses were then examined using factor analysis.

Findings – The study concludes that concerns about the industry’s future must be accompanied by a concerted effort to communicate and market the importance drugs play in improving and extending lives.

Practical implications – These will influence political factors that effect new drug development.

Originality/value – The study develops a list of potential major issues facing the industry over the next three to five years.

Keywords Pharmaceuticals industry, Drugs, Research and development

Paper type Research paper

Introduction

In the next few years, pharmaceutical executives worldwide will face a number of difficult issues ranging from a changing political environment, to drug safety, to the industry’s image and the viability of the current business model (Patterson, 2008; Rajamäki, 2008; Klein, 2008; Lopert and Moon, 2007). To ensure the pharmaceutical industry’s continued prosperity and to deliver improved health care, executives must consider these individual issues as highly interrelated pressure points requiring their immediate attention (Jarvis, 2007a, b; Zhong and Moseley, 2007; Yager and Starrett, 2006). This study summarizes the issues that pharmaceutical executives think their industry will face in the near future.

This two-phase study involved more than 70 senior industry executives from commercial operations and research and development (R&D). The participants



included company operational and R&D chiefs, top managers in marketing and clinical development, and important line and staff personnel. The study involved participants from many countries, but primarily North America and Europe.

In the initial phase, executives were asked to rank important industry issues; in the second phase, the study applied statistical techniques to discover links between the identified issues. This paper presents the study results, which offer an overview of how executives envision the pharmaceutical industry's future and the important challenges that lie ahead.

Overview

Prescription drugs represent around 10-12 percent of health care expenditures in most countries. Private and public spending on drugs slowed down in 2007 to its lowest growth rate since 1977, even though total prescription drug revenues have received a significant boost due to Medicare Part D. No matter the rate of spending increase though, the growing use of prescription drugs will bring even more attention to their use (Catlin *et al.*, 2008).

Drug development continues to become more expensive, manifested by a lower number of new drug applications (NDA) submitted by pharmaceutical companies (US Government Accountability Office, 2006). Moreover, the recent experiences with the safety of new drugs has slowed the rate of new drug development and concentrated public attention on the issue (Truelove, 2006).

At the same time, when new drug productivity is declining, and the costs of new drug development are increasing, the public's image of the industry is quite challenging. Many people do not easily accept the role of profit making in health care in general, and the pharmaceutical industry in particular (Olson, 2002).

Methodology

The study design

We conducted an online survey with 70 industry executives who agreed to participate in the study. Their titles ranged from Company President to Senior Director. Of the participants, 42 came from the commercial part of the industry, while 28 came from the R&D side. In total, 38 of the respondents were based in the USA, with another 32 participants located in Europe. Particularly noteworthy was the lack of statistically significant differences in the overall response patterns by participants' geographic or organizational location.

We employed a modified approach to the Delphi technique in our survey. The Delphi technique, a widely applied business method for obtaining forecasts from a panel of experts, is based on well-researched principles and provides forecasts that are more accurate than those from unstructured groups. The Delphi technique usually involves two or more rounds of opinion gathering, during which experts predict, or evaluate, a set of issues. The method combines the reality of limited information with the value of expert opinion, experience and intuition (Duffield, 1988). The modified Delphi approach in this study reflected the nature of the study content and the study participants.

Consistent with the Delphi methodology, the participants were anonymous to one another, ensuring that personalities, company, or management positions could not easily influence the results. The issues in the Delphi technique were drawn from a review of major pharmaceutical industry publications that identified the issues most mentioned in

these publications. Additionally, the study included a series of preliminary, open-ended, interviews with industry experts and pharmaceutical management to confirm the findings of the publication review, and to ensure that every important issue was included.

Based upon these initial activities, the study developed a list of potential major issues facing the industry over the next three to five years, with each Delphi participant being asked, by means of an e-mail questionnaire, to rate the relative importance of each of the issues facing the industry. Participants rated each of the individual items on a ten-point scale, with 1 being “not at all important” and 10 being “vitally important.” There were four versions of the initial questionnaire, with the items systematically rotated to insure that any potential question order bias was minimized. As part of the Delphi process, the results of the first round of questionnaires were presented to the participants, enabling them to see how their answers differed from those of the other participants.

The study’s Delphi process sought to focus on participants with answers significantly different from the average to determine if they knew something the others participants did not know. Once identified, these participants were asked to indicate in writing, or through an interview, why they believed their answers differed so clearly from the other study participants. This information was, in turn, shared with the other participants, and then all participants were asked to evaluate the issues again, with a resulting list of the individual items, and the relative final importance attached to each.

Factor analysis

The study also employed factor analysis to examine the underlying factors that might explain the correlations between the individual items. Factor analysis, which originated in psychometrics, is also used in economics, marketing, product management, and operations research. Factor analysis helped the study examine the nature of the thinking that gave overall structure to answers the participants provided to individual issues. While answers to individual items are, at times, just answers to individual items, some answers may also be the result of several underlying dimensions, or factors (Fabrigar *et al.*, 1999). We labeled these individual underlying factors as industry pressure points. Factor analysis provided the study with a perceptual map of what the participating industry leaders believed were the key issues, or “industry pressure points” the pharmaceutical industry faces today.

The study’s statistical methodology used a principal components analysis in its factor analysis, with a varimax rotation. The model accounted for a large 80 percent of the variance. The study analysis identified six underlying factors in its perceptual map of the issues the industry faces. The factors are summarized in Table II.

Key individual issues

Of the 14 important issues selected for analysis, six issues emerged as most significant. We considered an item to be of most significance if it received an 8, 9 or 10 on our ten-point scale from at least 50 percent of the respondents.

Industry image

Not surprisingly, the study found that industry leaders were very concerned about the industry’s image. In many developed countries outside the USA, market-based health care delivery remains an unsettling issue with large portions of the population. Yet, even in a more market-based economy like the USA, public opinion polls point to a

declining industry image. This diminished view of the industry, in developed and developing areas alike, makes it an attractive target for public leaders (Steinbrook, 2007; Dickinson, 2007; Ozdemir and Williams-Jones, 2006). According to one executive:

Many people seem uncomfortable with the combination of profits and health care. The pharmaceutical industry in particular has done such a good job coming up with new drugs that the growing costs of pharmaceuticals has become an easy target for the media and others.

Drug safety

Drug safety is of critical importance to the industry executives. Few issues have received more attention in the media than drug safety (Leiden, 2008; Keyhani, 2008; Anderson *et al.*, 2008). Yet, the issue of drug safety goes beyond the sensational news headlines of difficulties some drugs have encountered. It is associated with longer term and wider forces. For example, the study participants believed that changing demographic and economic trends will increase the demand for health services in general, and pharmaceuticals in particular. Furthermore, drugs will be increasingly necessary in the treatment of ever more serious medical maladies and the expectation is that drugs will treat these illnesses with fewer side effects. Health care is already considered a right in many developed areas of the world and risk-free drugs may also soon be considered a right at well. As one participant observed:

As we become richer, people will expect that drugs can improve their lives, and that means almost risk free drugs with few side effects. People will expect more. Drugs will do more. And however unrealistic, people will increasingly demand drugs to work with no problems.

Cost of drug development

Commercial and R&D executives consider the costs of new drug development to be of particular consequence. Costs are soaring due to larger and more complex studies, some of which are the result of increasing regulatory demands, but also a consequence of treating more difficult medical conditions. The head of development in one major company summarized the challenge: "My CEO says we must think of major changes in the way we develop drugs, not just to stop the growth in costs, but reduce them by 50 per cent."

Price regulation

The study participants considered the potential price regulation in the USA as a concern that may bring about unwanted industry change. They saw that regulation could limit patient access to pharmaceutical products and, in the long range, limit breakthrough drug innovation.

Political environment

The American political environment was another critical issue identified by the senior executives. A different political environment could influence pricing and patient access to pharmaceutical products and, in the long range, influence drug innovation.

Lack of new drugs

Executives in the study saw the potential lack of innovative new drugs as a major issue for industry management. As one senior commercial executive stated, "My main concern is how do we come up and sell new drugs that people can pay for" (Table I).

Table I.
List of individual issues
in order of importance to
the participants

Individual issue	Importance score
Pharmaceutical industry's image	64
Drug safety	59
Cost of new drug development	57
Potential regulation of drug prices in the USA	55
Political environment in the USA	50
Potential lack of innovative new drugs	50
Increased regulation of drug development	41
Increased regulation of drug marketing	34
Generic drug usage	32
Lack of intellectual property in key markets, i.e. China and India	32
Drug profits in the USA	30
Political environment in Europe	26
Drug profits in major markets outside the USA	23
Overall effectiveness of drug marketing	19

Note: Percentage of respondents giving an issue an 8, 9 or 10

Pressure points

Using factor analysis, the second part of the study focused on discovering how the senior executives in the study saw the relationship between the identified issues. The factor analysis provided a perceptual map of the 15 individual issues and yielded six key perceived “pressure points” in the coming years.

Each of the six factors in Table II represents a grouping of the closely associated variables that are perceived as exerting pressure on the future performance of the corporations managed by study participants. Mathematically, these pressure points (factors) are isolated; practically, it can be argued that they are influenced by each other. Although one pressure point, global financial results, specifically covers financial performance, the other five points can significantly impact revenue and profits.

Six pressure points

Pressure Point 1: society's perception of pharma

The study identified society's perception of pharma as a key pressure point (factor) because of the individual issues (variables) that loaded with the factor. Executives in the study were particularly sensitive to the industry's image, especially given the visibility of higher health care costs in general and prescription drugs in particular. Few patients understand that a small portion of that increased cost for prescription drugs is due to the price increases of existing marketed products. Instead, most of that increase is due to greater drug usage and the higher costs of the new, more innovative, drugs reaching health care professionals and patients. In addition, these executives highlighted the role that drug safety may have on the industry image.

Pressure Point 2: availability of safe new drugs

In essence, executives recognized that the costs associated with the tarnished image of the industry are driven in large part by society's perception that companies have not yet effectively dealt with the issue of drug safety. The lack of intellectual property in key markets, profits outside the USA, and generic usage are all bundled in this issue of the availability of safe drugs.

Individual issue	Factor					Global financial results
	Society's perception of pharma	Availability of safe drugs	Politics and legislation	Regulatory environment	Drug innovation and diffusion	
Potential regulation of drug prices in the USA	0.04	0.08	0.59	0.12	-0.01	0.49
Drug safety	0.12	0.74	0.28	0.14	-0.04	-0.14
Political environment in Europe	0.00	0.10	0.69	0.03	-0.18	0.10
Generic drug usage	0.17	0.86	-0.08	-0.02	0.09	-0.02
Increased regulation of drug development	0.03	-0.16	0.11	0.80	-0.10	0.02
Increased regulation of drug marketing	-0.08	-0.03	-0.12	0.82	0.15	0.26
Pharmaceutical industry's image	-0.77	0.13	0.28	0.15	-0.03	-0.22
Potential lack of blockbuster in coming years	-0.19	0.06	0.00	-0.07	0.83	-0.06
Potential lack of innovative new drugs	0.23	-0.04	-0.16	0.17	0.80	0.03
Lack of intellectual property in key markets such as China and India	-0.13	0.65	0.13	0.00	-0.07	0.21
Cost of new drug development	0.09	0.36	0.16	0.16	0.60	-0.08
Overall effectiveness of drug marketing	-0.03	0.06	-0.08	0.15	0.48	0.64
Drug profits in major markets outside the USA	-0.27	0.56	-0.04	-0.04	0.01	0.62
Drug profits in the USA	0.17	0.09	0.22	0.09	-0.20	0.82
Political environment in the USA	0.00	-0.09	0.91	0.01	0.02	-0.06

Notes: Extraction method: principal component analysis. Rotation method: varimax with Kaiser normalization. Rotation converged in seven iterations

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Table II.
Factor analysis: pharma
pressure points

The subsequent costs to the industry include the loss of revenue and profits from drugs that are pulled from the market (Baycol and Vioxx) and the funds spent in legal defense of those drugs. These costs divert resources from R&D and operating the corporation. As one executive stated, "Safety is always an issue, but transparency is more one."

Pressure Point 3: politics and legislation

The study found that Pressure Point 3 concerned the shift in control of the federal legislature and the degree of uncertainty that a changed political environment can produce. Executives have limited control over this issue in contrast to their control of safety and image issues.

Study participants believed that legislative outcomes could range from the potential revisions to the Medicare Modernization Act to the threat of restrictions on freedom of the direction companies take on medical research. They also saw other obstacles to growth and expansion, such as:

- Congressional attempts to dictate the direction of research that would have a profound affect on the speed of discovery and development of cures and prevention of current diseases.
- Laws establishing price controls within the USA that would impact on profitability leading to reduced resources dedicated for R&D.
- A potential ban of the "authorized generic" version of the products within the branded pharmaceutical, which would have an impact on the life cycle strategies companies deem appropriate to manage brands as they approach patent expiry.

Study participants also saw problems in the geo-political environment that may present a challenge to expansion. The largest developing markets are China and India with combined populations in excess of two billion. But, these developing economies cannot support the higher priced drugs required to generate profits and there is limited (or lack of) protection for intellectual property.

Understandably, the issues selected by study participants (variables) that load under this pressure point (factor) are potential regulation of drug prices in the USA; political environment in Europe; and the political environment in the USA.

Pressure Point 4: regulatory environment

This pressure point includes increased regulation of drug development and drug marketing. With the rising cost of bringing a drug to market (nearly \$1 billion) and the increasing time to approval (more than ten years) (DiMasi and Grabowski, 2007; DiMasi *et al.*, 2003), study participants saw increased regulation as a major concern. Some respondents, however, saw regulation as a way of life, with drugs ranking among the top of regulated industries. These respondents see additional regulation to ensure the safety, efficacy and proven therapeutic value of a drug as a concern but not an unexpected one.

Pressure Point 5: drug innovation and diffusion

The study executives saw increasing drug development costs as one of the greatest concerns for a viable future. They included in their responses variables such as the potential lack of blockbuster drugs in coming years, the potential lack of innovative

new drugs, and the overall effectiveness of drug marketing. They emphasized the escalating investment needed to bring new drugs to market, but also recognized that there may no longer be a time when a pharmaceutical firm has multiple blockbuster drugs within its portfolio. On the other hand, the executives in the study recognized that there is no shortage of compounds available for development, especially drugs to potentially license-in. Adopting new drugs will depend on their effectiveness and affordability.

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Study executives also expressed a concern for making the new therapy accessible to patients without payer support or placing the therapy on a high patient co-pay level. One respondent stated: “The need for greater innovation with spiraling costs and lack of blockbusters will require a change in the pharma business model.”

Pressure Point 6: global financial results

The issues linked to this pressure point are drug profits in the USA and in major markets outside the USA. They also indicate that they are concerned that traditional ways of marketing will not provide the profits necessary for continued innovation. The study executives have shifted their focus from “stakeholder to stockholder.” However, the recognition that historical levels of profitability will continue to be necessary to fund the new drug innovations, ties stockholder interests back to the stakeholder interests of the other pressure points.

Clearly, the industry’s financial growth rate has slowed in recent years. In fact, each of the study’s 15 variables could be said to have some impact on the flat to slightly positive industry growth. And the study concluded that the degree to which these variables influence the future of the industry is directly related to how these issues are addressed in the short term. One study participant responded:

[...] the largest problem is its (pharmaceutical industry’s) inability to document the value of its innovative products to third party payers, who are critical to the industry’s future prosperity; increasingly the customer is the payer.

Another participant stated: “one can only hope that America soon realizes that no profits equal no new drugs... it’s that simple.”

Conclusion

The ranking of the issues, the pressure points, and some of the commentary in the study present an uncertain future for the pharmaceutical industry. Pharmaceuticals will remain a very risky business as it relates to research, discovery, and development of new cures for diseases. But, as this study found, when we couple the inherent risks pharmaceuticals face with social, political, and economic unknowns, we compound the pressures executives face. Simply stated, the future of the pharmaceutical industry will depend on the direction of legislation, how the industry improves the way it is perceived, the availability of safe new drugs, and creative ways to market existing and new drugs. Industry executives have limited control of the political environment; influencing the latter will require a concerted effort to communicate and market more effectively the benefits of prescription therapy in extending and improving the quality of our lives.

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