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Clinical Trials: A Branding Opportunity?

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Abstract : The marketing of prescription medicines is constrained by restrictions on promotion, product complexity and short lifecycles. Pharmaceutical companies face major communication challenges to ensure Health Care Professionals (HCP) are knowledgeable about their licensed medicinal products. Branding overcomes some communication limitations of prescription medicine marketing and Opinion Leaders are viewed as effective communicators of evidence based brand value to the HCP. Through structured qualitative interviews, we examined how the clinical trial process supports branding and how this process might be modified to optimize such a benefit. Trial participation was seen to be an effective way of giving HCP the insight and knowledge to become Opinion Leaders.

I INTRODUCTION

In the pharmaceutical industry, branding is complicated by short product life cycles, the complexity of products and the limitations imposed by regulatory authorities on communication of only the officially sanctioned basic evidence-based benefits of the drug. Patent restrictions and the constant risk of redundancy due to development and license of superior competitors means that product life cycles are short. The drug as a product is unique and complex in that its full properties are rarely known at the time of license. This may be related to long-term benefits of the drug and safety data that may take years of use or additional studies to identify. There may also be benefits in relation to other diseases or patient populations, which hitherto have not been contemplated or studied. There is in addition a recognized information overload on HCP. This means that they increasingly rely on peers and industry for education and guidance. The customers need not just to be medically qualified but increasingly require additional training to gain an understanding of the products to ensure optimal and evidence based use. The market for prescription drugs is restricted in many ways. The products (medicines) are

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worthless without a license to sell and promote them for use in a specifically designated patient population. The selling of medicines to the prescribing physician is additionally unusual as physicians are not the end-users and beneficiaries of the product. Moreover, advertising directly to the patient is not permitted in Europe. One communication tool available is branding. In most industries, branding plays an important role in conveying product benefits to the customer via symbols or names which trigger positive associations, sometimes rational and sometimes irrational. In addition to the complexity of the products, the role of branding in the pharmaceutical industry has particular complications due to the reasons described above. Clinical trials are required by local and international health authorities to assess the safety and efficacy of investigational products (unlicensed medicines) for approval for use in designated patient populations. Though clinical trials and brand effect have been published by academic scholars (Branthwaite and Cooper, 1981; Urde, 1994; McAdam and Barron, 2002), clinical trials and branding literature has been concentrated in general medical and pharmaceutical journals (Delagneau, 2004; Miles, 2005; Radulescu, 2005). The research addresses (1) how the clinical trial process itself supports branding and (2) how this process might be modified to optimize such a benefit. The study was conducted using qualitative interviews with key senior management of a leading biomedicines company. This paper will concentrate on prescription drugs in the EU, since prescription medicines contribute around 90% of global pharmaceuticals revenue (Blacket and Harrison, 2001) and direct to consumer advertising regulation differs in EU from the US.

II BACKGROUND AND REVIEW

A. The Pharmaceutical Industry

Two key developments have contributed to the current state of the modern pharmaceutical industry. First, technological and scientific advancements have enabled a boom in the discovery and production of drugs. Second, escalating concern over the role of pharmaceutical company responsibilities and the safety of medicines in their production and use has generated an increasingly restrictive regulatory environment. Both developments have, undoubtedly, improved the safety and efficacy of medicines used on patients, but they

have also increased cost of development. Clinical trial programmes have become larger than ever due to increasing demands of licensing agencies for safety and efficacy data. The marketing mix, often used to facilitate meaningful measurement of marketing efforts and their worth, continues to be one of the predominant marketing theories in pharmaceutical and medical marketing (McCarthy, 1960; Stibel and Kapoor, 2002; James, 2004; Kolter, Armstrong, Saunders and Wong, 2005). The brand of a product triggers specific responses in the minds of the customer (e.g. aspiration, expressive and imaginative) (Kolter et al, 2005). A product is made in a factory while a brand is sold in a shop. Brands have core customers who remain loyal even after occasional (redundant) problems. Brands usually build on quality products and theoretically, they are very difficult to imitate. Often viewed as part of the product, —brand is also a part of communication strategy and in fact serves as a useful integrative force bringing product policy and communication closer (Shapiro, 1985). Van Waterschoot and Van den Bulte (1992) recognize that promotion is not a sole preserve of communication, and but also includes persuasion. For analysis of the value of clinical trials to the customer, this study employed the Van Waterschoot and Van de Bulte (1992) model, which incorporates many of the criticisms identified in the original McCarthy model (McCarthy, 1960) while retaining a simplicity which makes it ideal for this type of analysis. Kotler's et al (2005) perception of product levels and the incorporation of branding were included in the analysis. Alongside these models, this study also employed the relationship marketing concept because of the interactive process of a clinical trial and the importance of relationship to healthcare marketing (Gronroos, 1994; English, 2000; MacStravic, 2000; Moller and Halinen, 2000; Wright and Lundstrom, 2004). Logistics is noted as an important part of the process but it has little direct effect on the clinical trial outcome, so we do not discuss this in detail.

B. Brand And Communication

Brand and communication provide the level of benefit that is suggested or believed by a customer either to exist or felt to be imminent in the future, including faith and trust. Nevertheless, these elements are not necessarily being delivered to the customer. Despite being a data orientated and evidence-based industry, physicians are still customers who are as prone to perceived benefits as other consumers are. Brand is also about feelings, a relationship with the drug and the company behind it. Brand is not an easily imitable differentiator because relationships are experiences and experiences are unique. In an industry that produces products that could potentially harm patients, the use of such emotional communication with physicians can raise some ethical questions. Physicians in the 21st century are faced with a daunting challenge of keeping

abreast with medical advances. There is an enormous volume of scientific information in medical journals (almost 4,000 titles) making it impossible for practitioners to keep up with all research, even in specialties. Medical education programs are therefore essential to help practitioners stay on top of the literature. Whether the education sponsor is a pharmaceutical firm or an academic source, each has the same goal of enhancing the practice of evidence based medicine within designated labels. In the pharmaceutical industry, major means of mass communication are through journals, conferences and local hospital educational forums which are the natural communication channels used by the medical community. Local medical communities have small cadres of readily identifiable physicians who are influential in facilitating new learning and adoption of advances. Hence, clinicians respond to new clinical interventions by seeking information and opinions from peers and opinion leaders rather than necessarily assessing the scientific merits by themselves (Dumovic and Vries, 2004). Opinion leaders are perceived as technically competent, authoritative, independent, dedicated and esteemed members of a local group. The communication of evidence based on-label information from companies plays an important role in patient care. During one study in the United Kingdom, general practitioners were asked to cite the most important sources of information for drugs and 42% referred to pharmaceutical industry education and 36% referred to hospital consultant recommendations (Dumovic and de Vries, 2004, Wright and Lundstrom, 2004). Publicity communication ensures that third parties have a positive and informed view of the product and company. Third parties increasingly have a greater influence over industry via press, pressure groups and politicians. The public and press, due to its associations with profiteering from illness, often see the pharmaceutical industry in a negative light. Patients are becoming increasingly organized as pressure groups that exert force on companies, which can have a negative effect on business. They can also pressure governments to release funds for treatment, which can have a positive effect on business. Some marketing guides to the pharmaceutical industry make a particular point in this aspect of the industry by adding patients and politics to the marketing mix.

C. Pharmaceutical Branding

Thomas Beecham is accredited with one of the first pharmaceutical branding exercises when he affiliated his own name with an effective new laxative in 1842 in order to make it stand out from a plethora of other products on the pharmacists' shelves (Anderson and Homan, 2002). For pharmaceutical manufacturers, the traditional sources of value creation have laid in successful research and development. Blacket and Harrison (2001) indicate that the industry continues to maintain various conventional supply-driven characteristics overlaid with government paternalism. One symptom of this is the observation that mergers and acquisitions in the pharmaceutical industry take place to acquire pipelines but not brands. The pharmaceutical companies are conspicuously absent from inter-brand leagues. Corstjens and Carpenter (2000) argue that as there is increasing competition between drugs, none of the top ten selling pharmaceuticals have been judged by the FDA to offer "important therapeutic gains over existing therapies" and so that pharmaceutical industry should take a lesson from the fast-moving consumer goods industry. Consumer goods manufacturers have responded to product proliferation and falling margins by building strong brand identities. For consumer goods, efforts are made to build and preserve brands and present changes as "improvements and refinements". Moss and Schuiling (2004) believe that the pharmaceutical industry have not realized that they manage Brands not just products. The industry has to remind itself that customers stock, dispense, prescribe, buy and use brands, not products (James, 2004). The brand is an integral part of the benefit process central to the business of customer satisfaction and to build and retain customer loyalty. People have a deep emotional connection to their health. Brands add a greater sense of purpose to the treatment experience, as brands are trusted and are something in which the patient or physician puts their faith. Therefore, there may be a need for the pharmaceutical industry to invest in long-term corporate and product brands (Corstjens and Carpenter, 2000; Moss and Schuiling, 2004). Stibel and Kapoor (2002) point out that only Pfizer and Johnson & Johnson have managed to make products and corporate brands benefit each other. Schroff (2003) argues that as the pharmaceutical industry currently maintains a bad image corporate branding is unlikely to be beneficial. He argues that few consumers would be able to identify the pharmaceutical company that has the best record on reporting safety to authorities and a physician will rarely be asked by a patient about the maker of a drug. Nevertheless, corporate branding may help a drug representative gain access to physicians.

III THE STUDY AND FINDINGS

This research was conducted via structured qualitative interviews with seven key senior managers of a leading biomedicine company in Europe. The seven interviewees held positions as Vice Presidents (Interviewee 4 and 5), Executive Director (Interviewee 7), Senior Director (Interviewee 2), Director (Interviewee 6), Associate Director (Interviewee 1) and Senior Manager (Interviewee 3) of Global Marketing, Medical Affairs, and Research. During the primary research, there was no attempt to quantify data but it was utilized as an attempt to trigger opinions on specific subjects. The questions were identical in content and order, since a standard script was utilized. Prior to the interview, all participants were given a PowerPoint presentation, which provided background and definitions, and guided the participants through the interview questions. All interviews were recorded and then transcribed.

A. Importance of Product Branding

The literature has previously highlighted the debate on the value of product branding for pharmaceutical products. Examples of product brand value statements were put before the interviewees and all agreed with the statements. Interviewees 1, 2, 3, 4 and 7 strongly agreed with the value of product branding of pharmaceuticals.

"You have to appeal to [doctors] not only as scientists but as consumers ... we sometimes shy away from the emotional elements because we think they just want the facts, I think its a balance." (Interviewee 4) "[I could] not think of anything more emotional than ones health." (Interviewee 7)

Interviewees suggested that it is not possible to separate fact from emotion when selling medicines but emphasis was made on the trust aspect of medicine branding. After all, doctors are also consumers in their private lives. Although it was highlighted that branding is only possible if you are not misleading the customer (Interviewee 6). Branding is considered less important if there is no competition but is a very effective way to reduce barriers to entry (Interviewee 3). It was also highlighted that brands can be positive as well as negative (Interviewee 1).

B. Importance of Corporate Branding

Wright and Lundstrom (2004) identify three values of a sales representative, with which a physician forms an overall impression. These values include a representative's characteristics, ethics and perception of the pharmaceutical corporation he or she represents. Hence, corporate image and branding could be seen as important competitive tools for medicines. Interviewees were asked if they thought that corporate branding was important.

“Pharmaceutical companies have done very little or nothing over the years to identify themselves either corporately or pharmaceutically by product although that has changed in the last decade or so with direct to consumer advertising, certainly in the US. Instead of creating our own image and how we want to be perceived we have let [the media] do this for us and that’s the worst thing that can ever happen” (Interviewee 4). —*I like to think that people looking at us from the outside think “That guy’s from [the company], that’s the ethical company that tells me about problems before I read about it in the news.’ If people think good things about our company because they know what we are about then that obviously makes our products more attractive and powerful... it’s all about honesty”* (Interviewee 7).

In summary, it was agreed that the corporate brand is seen as a way to encapsulate the companies’ ethical position which is good for all of its products. It was additionally pointed out that to have a good reputation a corporation will also enhances relationships with opinion leaders (Interviewee 3).

C. Importance of Opinion Leaders as Communicators of Brand

As discussed, opinion leaders work with pharmaceutical companies to communicate information about drugs and are specifically sought out by peers for advice. Since doctors are unable to stay on top of the medical literature, they rely on well-informed peers to guide them. Interviewees were introduced to the concept that opinion leaders are in fact in many ways communicators of brand value. This notion was accepted.

“Ultimately [with] third party people ... [such] testimonial has high value. A trusted personality conveys trust on to the product.” (Interviewee 7). *“Opinion leaders are huge... their reputation and their credentials and their credibility in the medical community ... they are the most important people to have on your side.”*(Interviewee 4). *“I agree that opinion leaders convey features of brand but positively and negatively, it’s about trust and how data gets interpreted.”* (Interviewee 5).

However some interviewees did raise caution on the value of opinion leaders, pointing out that they often try to advocate several products (Interviewees 1 and 3). In summary, it was felt that opinion leaders are sought out for assurance. Although this may take the form of hard clinical data, it also involves trust and faith in their opinion. These intangible features reflect the value that brands seek to communicate. It can be concluded from this that opinion leaders are human manifestations of brand value with the limitation that in a competitive environment they might represent several companies and will therefore seek to maintain these relationships by remaining as impartial as possible.

D. The Process of Clinical Trials Supports Corporate Brand Value

Prior to approval, a potential drug is known as an investigational agent and no product branding is used. After approval the drugs brand name is more widely known but never used in the context of a clinical study so as not to promote off-label usage. Both corporate and product brands may benefit from both the processes and the outputs of a study. It exposes the opinion leaders or future opinion leaders to regular contact with both the investigational agent (future drug) and the company. This achieves familiarity under perceived safer conditions of an ethically approved clinical trial and also allows a quality relationship to develop with the people behind the product. Knowing the people behind the drug on a personal basis is preferable to building a relationship with a faceless pharmaceutical company. The interviewees comment on the above:

“It’s a chance for a physician to see inside a company ... they get a good view as to the kinds of people that we hire, the kinds of philosophies that we live by, the ethics ... the scientific credentials of [employees]” (Interviewee 4). —*“You need to have an important question to ask ... if you are doing a trial with an important endpoint and important healthcare question, being involved with it brings people up to speed. [Doctors in a trial] become from neutral to very passionate to what [the investigational agent] and [the company] are about.”* (Interviewee 7) *“[The brand value lies] much more in the innovation of the questions you ask. [Future] product branding has a significant value if it has been built on strong clinical data. I do not believe that corporate brand value translates into competitive advantage for a product. Customers use a product due to the product, not the company. Corporate branding can have a negative value if the company has been associated with something negative, eg a safety scandal. Positive corporate branding may help the launch in new products”* (Interviewee 5) *“[The] clinical trial is the best opportunity for a bad or very good first impression”* (Interviewee 2). *“We are judged on whether we are performing cutting edge science or not”* (Interviewee 5)

In summary, the interviewees generally agreed that there are clear corporate branding opportunities, which can be created by encouraging physicians to participate in clinical trials and by being exposed to the clinical trial process. This view supports Dumovic and de Vries (2004) suggestion about clinical researchers’ suitability as Opinion Leaders.

E. Execution of Clinical Studies

Since the opportunity for opinion leader development has been identified in the literature, interviewees were asked whether all investigators should be supported to develop into opinion leaders and if so,

are current organizational structures appropriate for this to take place in their company. Typically clinical studies are out-licensed to Contract Research Organisations (CROs) to take on the operational task of executing the research and the staff members of the company are not necessarily in touch with the study itself. When the interviewees were questioned on the dilemma of being in contact with the actual study to support the corporate brand versus the practicality of running the study via a CRO, the following responses were obtained:

"The main contact I think that should be [the company] to ensure full branding value ... however for the monitoring I do not see the need to have that done by a [the company] person" (Interviewee 3) *"[Taking on trial operations is] not practical. You can still realize the brand value without being connected at every step"* (Interviewee 4). *"CROs are agents of us. Companies do need to take an active role. A company that hires a good CROs that acts as a third party that is known for quality is a good reflection on the company ... But at the end of the day we are [the company] not [the CRO]"* (Interviewee 7). *"I think companies will always care more about their customers than imported vendors"* (Interviewee 6). *"It is critical that Marketing, Clinical Operations and Medical Affairs are aligned to build and execute strategy. Each group adds value to opinion leader's development"* (Interviewee 5).

Relationship marketing literature stipulates that all parts of an organization must embrace the conversation with the customer (Gronroos, 1994; English, 2000; MacStravic, 2000; Moller and Halinen, 2000). Therefore, if full responsibility of the clinical study process is not practical, the company may benefit from closer liaisons between the departments in the company. Blacket & Harrison (2001) and Redmond (2001) suggest that the commercial team of a company must be involved with the clinical team to position the vision of branding from the early phase of the products life cycle. Interviewees suggested:

"Internally we should communicate optimally about who is doing what with which opinion leaders ... but not everyone needs to know everything. Medical Affairs and Marketing should work very closely together ... medical education is really a marketing tool" (Interviewee 3). *"If we do not have a process in place on how Medical Affairs, Marketing and Clinical Operations should engage ... we will fail"* (Interviewee 1) *"The opinion leaders have many needs and no one can serve all those needs. It really takes a highly unified team ... to service the needs of the customer. It is a combination of Marketing, Medical Affairs and Clinical Operations working as a unified consolidated team leveraging every resource that they can that delivers the highest value to the customer"* (Interviewee 4) *"Everybody needs to be made aware and wear the [company] cap... to external*

people we are all the one and the same. You want to encourage everyone, as appropriate for their role, to work with [opinion leaders] to appropriately direct their questions and queries in a prompt fashion ... everybody bears this burden. I think in industry sometimes opportunities are lost because they are not really seeing their role as supporting what the company as a whole is doing but have a very silo'ed approach" (Interviewee 7). *"Why don't [companies engage in customer relations]?" – Marketing drugs is immensely complex. The reasons companies do not have joint customers relation strategies [between departments] is that it is too complicated, people simply do not have the time to build customer relations"* (Interviewee 2)

There is thus a clear sentiment of the need for relationship marketing, coupled with a realistic acceptance that perfection may not be attainable due to resource practicalities.

IV CONCLUSIONS

In the pharmaceutical industry, the corporate brand supports the product brand. Product branding of medicines is generally seen as an important aspect of communication. Opinion leaders personify brand values and augment the communication mix at all levels. Interviewees in this study accepted the role of the opinion leader as a communicator and as an important aspect of brand value. So the opinion leader is a key medium to transmit intangible faith in the product and they can do this at all levels of the communication mix: personal, mass and publicity. This faith must be based on evidence-based fact and not generate any perceptions that would encourage use beyond the label. Branding as a concept is thought to be ethical as long as its messages do not deviate from the evidence. Product brand equity is generally felt to be built on the initiation of good scientific questions. Corporate branding is thought to be supportive of the product brand and help communicate the trust that is needed to sell the products. Corporate brand equity is built by activities that generate respect for the company. The outputs of clinical studies in this respect are three-fold. Firstly, the registration studies form the foundation of the product brand (no promotion can be undertaken until this data has been officially sanctioned). Secondly, non registration studies, if scientifically sound and addressing unmet needs can also be significant contributors to brand equity – but must not be used to promote off-label use. There is a natural progression from the registration studies, where the brand is established, to post registration studies where non-licensing trials can continue to deliver significant brand value. Thirdly, negative outcome studies are not necessarily detrimental to the brand as long as it is not very unexpected. The corporate brand can indeed even

continue to be built from a negative outcome of a study that has been conducted in a rigorous scientific fashion and communicated openly. The process of a clinical study as far as the participating physician is concerned should be a highly positive experience and builds a close relationship between the physician with both the product and the company. The value that an opinion leader conveys as a communicator at all levels can in many ways be compared to the features that brands themselves seek to convey to its audience: faith, trust and value. It is therefore concluded that the physicians participating in clinical trials are good candidates for opinion leader development. A negative study outcome does not necessarily harm a product brand but a negative study experience will. Physicians with a negative impression of the company may convey this through peers and other communication forms and as a result harm the product brand.

V LIMITATIONS OF THIS STUDY AND FUTURE STUDY RECOMMENDED

This paper is only based on a small number of interviews. Ideally, the target of the brand messages should also have been questioned. A larger study could include customer surveys on the influence of clinical study participation on brand values. It is difficult to generalize across therapeutic indications as the benefit-risk considerations made by physicians differ and as such the influence of brands may vary. The nature and size of clinical studies also varies greatly across different medical disciplines. A clear extension of this study could include an analysis of the types of clinical studies required for different phases of the product life cycles. The registration studies establish the brand, but it would be interesting to explore whether there are different strategies of brand building through clinical studies that might be pursued at different stages of the life cycle. Included in this could be the consideration of patent extension strategies.

Important Note

This is a theoretical exercise and it must be noted that all promotion of pharmaceutical products must be within the product labels and branding cannot claim or suggest benefits beyond these. The results presented are within the scope of theory and do not represent the business practice of authors, interviewees or affiliated organisations, past, present or future. This paper does not condone off- or pre-label promotion, direct or perceived. All medicinal promotion should always be evidence-based, ethical and on label.

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