The Changing Landscape of Branding Pharmaceutical Assets

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Brannon Cashion
Global President
bcashion@addisonwhitney.com

Vince Budd
Senior Vice President
vbudd@addisonwhitney.com

Andrew Cuykendall
Vice President
acuykendall@addisonwhitney.com

Danny Plaisance
Vice President
dplaisance@addisonwhitney.com
OVERVIEW

Branding means a lot of different things to a lot of different people, but in its simplest form, a name is the face of a brand. Just as people have names – something we’re recognized by and called – so do pharmaceutical brands.

For this whitepaper, we’ll focus on the practice of naming an asset and how this process has evolved over the years. Branding is the construction of an identity, and a continual process, but at the foundation of every brand is its name. A strong brand name can convey a number of things like quality, reliability or clarity. By focusing on just the naming in this whitepaper, we’re able to break down some of the more complicated aspects of branding an asset and the changing regulatory landscape’s implications on naming.
AN INTRODUCTION TO PHARMACEUTICAL BRANDING

Before initiating a branding exercise, it is essential for internal teams to be up-to-date on global regulatory guidance. Without knowledge and understanding of current regulations, the entire process could result in rejected brand names and a lot of frustration. Familiarity and adherence with regulatory guidance paves the way to a brand’s success.¹

Pharmaceutical naming begins by identifying white space, or possible opportunities, based on the competitive environment, trends within a therapeutic class and trademark activity. This sort of research produces baseline data on messages already in the marketplace and which companies “own” those messages and to help identify potential opportunities for the asset’s brand. From here, it’s smart to build out an overall naming strategy that includes a variety of potential word associations and naming paths, from descriptive to creative. If budget and time are available, eliciting direction from the target audience can help identify naming stimuli, unmet needs, etc., relating to the asset.

With word associations and naming paths identified, brand name development begins. This process includes several rounds of brainstorming and list creation to arrive at the strongest options for the asset’s brand. Customarily, a brand development team will explore a variety of ideal functional and aspirational brand attributes, benefits, imagery and associations to create potential name candidates. In conjunction with the client team, the brand development team establishes guidelines for which word parts and concepts to explore and which ones to avoid and begin developing names within those guidelines.

¹Note: This paper was written in May/early June 2014 and is based on existing global regulatory guidance at that time. Given the dynamic nature of the regulatory environment, we recommend familiarizing yourself with the latest guidance before embarking on the pharmaceutical naming process.
Once names are created, the next step is to screen them against the developed naming strategy. At this point, since the names haven’t been thoroughly vetted yet, screening entails more cursory searches than in-depth research, which happens later in the process. Then, initial legal searches are conducted on any names that make it into further testing.

At this point in the process, comprehensive testing and research should be conducted. The information and insights from this research provide the content to help pharmaceutical companies build submission whitepapers to support the safety and viability of the asset’s proposed proprietary name.

An outline of research that should be conducted is below.

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<tr>
<th>Trademark Availability Screens</th>
<th>Linguistic Evaluations</th>
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<tr>
<td>Trademark availability screening should be conducted on all names in consideration using screening tools and databases. Screening should be conducted in all applicable geographies. Such screens are an essential part of the process, to ensure that a name candidate that has an obvious trademark conflict is avoided.</td>
<td>These evaluations test names in any market where the product will be sold, as well as in the languages spoken in those respective markets. Even if a drug is only going to be marketed in the United States, tests should still be conducted for Spanish, French Canadian, Chinese, Hindi, Arabic or any other language prevalent where the drug will be sold. These evaluations identify cultural or religious issues around the names, as well as negative connotations, slang issues and direct semantic translations.</td>
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<tr>
<th>Phonetic Orthographic Computer Analysis (POCA)</th>
<th>Medication Error Prevention and Analysis (Look-alike/Sound-alike Testing)</th>
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<td>This analysis is a U.S.-only evaluation that tests for phonetic and orthographic similarity to drugs currently or previously marketed in the United States.</td>
<td>Look-alike analysis is the evaluation of handwritten and electronic scripts. The handwritten scripts include cursive, block letter and a multitude of scripts based on various handwriting differences. Sound-alike analysis is the evaluation of how names are pronounced based on other drugs currently on the market.</td>
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**Best Practice?** At a minimum, conduct name safety testing in markets with established name review processes.

This robust research process isn’t necessary for every pharmaceutical company, but it is the best practice and a standard for consideration. It’s common practice to get the asset’s branding team comfortable with three to five names to have a back-up in the event of unforeseen regulatory challenges during the final name review and approval process.
THE EVOLUTION OF PHARMACEUTICAL BRANDING

OVERVIEW

The process followed by drug manufacturers in naming assets is very different now from 10 to 15 years ago. The most important factors we’ve seen in the evolution of pharmaceutical naming include:

- Name rejection rates by regulatory agencies are at an all-time high;
- Class 5 trademarks2 are about 400 percent more cluttered than in the past;
- Direct-to-consumer advertising has shifted to end-benefit or naming concepts more easily recognized by patients rather than entirely focusing on the healthcare professional audience;
- Promotional rejections are increasingly more common;
- Unique or unusual names, such as names that begin with or include two unlikely consonants paired together (for example: “Qsy-” or “Vyn-”) are more common now to create more unique names for regulatory approval.

INSIGHTS AND OBSERVATIONS

There has been a lot of talk in the industry about individual versus umbrella (or company) brands (see Pharmafile3 and Fast Company4). Big Pharma companies5 continue to be attached to individual pharmaceutical brands. These companies are reluctant to overly link their corporate brand too closely to a product brand to avoid negative public relations fallout from an unsuccessful product and to enable a diversified portfolio.

Where we do see corporate branding changing is at the therapeutic level. Companies are now building their corporate brands around a particular expertise, such as oncology, diabetes, cardiovascular, respiratory, or others. This change is concurrent with companies increasingly focusing on a narrower range of therapeutic areas and selling off assets that no longer fit this focus. (Company A sells its diabetes portfolio to be able to better focus on oncology assets). Such portfolio reorganization helps companies increase efficiencies and better align their corporate brand around therapeutic-area-specific products and pipelines.

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1 Class 5 trademarks include pharmaceutical and veterinary preparations; sanitary preparations for medical purposes; dietetic substances adapted for medical use, food for babies; plasters, materials for dressings; material for stripping teeth, dental wax; disinfections; preparations for destroying vermin; fungicides, and herbicides.
3 “Big Pharma and the Value of the Umbrella Brand,” Fast Company, March 17, 2011
Meanwhile, there has been some shifting in the target audience for product names. In the past, pharmaceutical companies developed communications targeting primary care doctors who refer patients to specialists. Today, in an age of heightened technology and greater access to information, many branded assets are targeting messages directly to patients, as well as physicians. Such communications help consumers become more informed about their conditions and treatments.

Names are becoming longer and more complex as time goes on. Since we are still creating names with the same 26 letters that have existed for some time, finding unique letter configurations and sounds becomes harder every day.

There are two main reasons why. First, the whitespace for identifying and owning a trademark is getting smaller as companies are filing more and more trademarks to protect their brand names. Companies also want global names, and with more countries having stronger guidelines for name approvals it is harder to come up with a name that will work across different geographies. Navigating both hurdles, the increase in trademark filings and the desire for global brands has forced companies to explore names that are more unique than in the past.

Secondly, 20 years ago you didn’t have small biotechs filing trademarks, but now everyone is from small pharmaceutical and up is filing their own trademarks. Again, it’s a volume issue. Emerging pharmaceutical companies are taking drugs farther into development and even into commercialization depending on how mature the market is. As diseases and indications are more narrowly defined there isn’t a need for Big Pharma to take on the drug like there was in the past.

Finally, technology has had a remarkable impact on pharmaceutical companies and how they approach their branding strategies, just as it has in other industries. The name of the game here is knowledge. With the rise of tablets, other mobile devices and an overall increase in the availability of information, there has been a considerable decrease of the somewhat antiquated sales rep/doctor relationship. Chat rooms, group advocacy, patient assistance programs, social media and other technologies have allowed healthcare professionals to become far more educated about a drug, compound and/or biologic in the pipeline. And, since patients have many of these same tools to research treatment options, they are not only paying more attention to their health and wellness, but they are proactively reaching out to their doctors about treatments and potential clinical trials to participate in.
Brands can live in a number of places because of our social world and has greatly increased brand exposure. For naming, we have to take into account where this brand will live and who the primary audience will be. Pharmaceutical companies are no longer only marketing their brands towards healthcare professionals.

THE GLOBAL REGULATORY ENVIRONMENT: GETTING A NAME APPROVED

Similar to how we set up the overall pharmaceutical branding process, we’ll also baseline the current regulatory landscape. For the purpose of this section, we will focus on four regulatory agencies: FDA (Food and Drug Administration, U.S.), EMA (European Medicines Agency, EU), Health Canada and PMDA (Pharmaceuticals and Medical Devices Agency, Japan). As is expected, there have been changes in the guidance of each agency since they were first established. The good news is, communication by the agencies to sponsors and branding firms has improved. As rules and regulations change, the regulatory bodies are being much more transparent and becoming stewards for patient safety.

Perspectives have evolved, too. There is more attention paid to a global viewpoint on naming – companies are working to develop names with less risk in markets outside of the above mentioned regulatory agencies’ countries. Also, there is more agency unification on how assets are reviewed, evaluated and critiqued. The agencies’ submission processes aren’t the same, but they have become similar, making it a little less difficult for pharmaceutical companies to apply for formal approval. Finally, there is much more focus on orthographic or phonetic similarities between names. This has consistently become the top priority for these agencies as they evolve their regulatory processes.

Taking a quick look at each agency, the FDA has become more collaborative and transparent with the industry overall. The FDA has started to engage much more regularly with the EMA, Health Canada and the PMDA regarding best practices. The FDA has always done its best to lead the industry in regulatory guidance and Health Canada’s recent guidance changes have stemmed from the FDA’s influence.
Canada has become a major player in regulation and has put new policies in place to reflect its growing market. Health Canada has made significant advancements in its nation’s guidance as a reflection of its complicated system and desire to streamline and raise awareness of its approval process. During the first half of 2014, Health Canada launched new guidance requiring a representative sample of healthcare professionals involved in the prescribing, dispensing and administering processes for a new drug to participate in a study to evaluate the safety of a potential proprietary name for submission. By mid-2015, Health Canada will have the most clearly defined methodology for name submission guidelines of any regulatory agency worldwide. Where the FDA and EMA encourage certain submission requests, Health Canada requires them.

The latest news from the EMA is the recent decision that drug manufacturers will no longer be able to submit four names for approval; companies will only be able to submit two names for review at one time. This new guidance will come into effect January 1, 2015 and the full details can be found via the EMA’s guideline via the footnote below.6

The new regulatory landscape has a lot of potential outcomes, but here are a few things that should be considered:

- A pharmaceutical company may want to get its names approved through the EMA before approaching the FDA
- Or, companies may submit review submissions concurrently to try to save time (and take a chance that the EMA will approve one of the same names submitted to the FDA)
- The process to get the same name approved by the EMA and FDA could take considerably longer than it does now
- Most notably, these changes could mean that companies will strategically create two separate brands for their assets: one for use in the U.S. and one for the EU

CONCLUSION

In conclusion, as new molecules, biologics and branded generics are developed and submitted each year, recognizing the evolution of the always changing regulatory and trademark environment is crucial to launching successful brands. Applying a disciplined process based on industry knowledge to every branding effort will help insure global clearance and approval for a sponsor of a newly proposed product.

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6 “Guideline on the acceptability of names for human medicinal products processed through the centralized procedure,” European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), May 22, 2014.
ABOUT THE AUTHORS

Addison Whitney Health’s senior leadership team is comprised of Brannon Cashion, global president, Vince Budd, senior vice president, and vice presidents, Andy Cuykendall and Daniel Plaisance. Their combined experience spans 60 years and work with all of the top 50 big pharmaceutical companies. With projects ranging from brand name development and clinical trial branding, to scientific branding and logo and package design, this Addison Whitney Health team is an industry leader in combined knowledge, professional acumen and passion.

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ABOUT ADDISON WHITNEY HEALTH

Addison Whitney is a global branding firm specializing in verbal and visual branding, brand strategy and market research. Founded in 1991, Addison Whitney’s depth and breadth of clients reaches across multiple industries, including consumer, B2B, technology, finance and hospitality. Addison Whitney Health, a specialized division of Addison Whitney, is a global leader in pharmaceutical and healthcare brand development. Utilizing a unique and interactive creative process, Addison Whitney has developed some of the world’s leading brands. Headquartered in Charlotte, NC, Addison Whitney has offices in New York, Seattle, London, Munich and Tokyo; for more information, visit www.addisonwhitneyhealth.com.
REFERENCES

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