ADDISON WHITNEY
INVENTIV HEALTH

THE CHANGING LANDSCAPE OF BRANDING PHARMACEUTICAL ASSETS: A FOCUS ON ONCOLOGY

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 white paper, 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. Over time a strong brand name can grow to be synonymous with a number of things like quality, reliability or clarity. To someone unfamiliar with pharmaceutical branding, drug names seem like words consisting of randomly strung together letters that result in an uncomfortable sounding and hard to decipher word. But those responsible for creating those names know those letters have a distinct and purposeful role and there is no therapeutic area where this is truer than oncology.

The process for drug naming remains the same across all therapeutic areas, but what does change when naming in oncology is the naming strategy. Throughout this process it is important to equally understand the steps involved in naming your asset, the creative output you'll receive and the current regulatory landscape for getting your name approved.

PHARMACEUTICAL BRAND NAMING: AN OVERVIEW

Name Development

- Naming Strategy Workshop
- Naming Strategy Report
- Name Creation
- Legal Trademark and Global Regulatory Prescreening
- Medical Panel Evaluation
- Global Linguistic Evaluation

Name Evaluation

- Phonetic and Orthographic Analysis (POCA)
- Market Research to Address Regulatory and Marketing Criteria

Regulatory Submission

- Preparation of Regulatory Submission Documents

Before initiating a brand naming 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]

[1]Note: This paper was written in May/early June 2014 and is based on existing global regulatory guidance at that time.

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 critical to build out an overall naming strategy that includes a variety of potential word associations and naming paths, ranging 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 name development team will establish guidelines for which word parts and concepts to explore and which ones to avoid and then will begin developing names within those guidelines.

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 screens 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 white papers to support the safety and viability of the asset's proposed brand name.

An outline of research that should be conducted is below.

Trademark Availability Screens

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.

Linguistic Evaluations

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 sematic translations.

Phonetic Orthographic Computer Analysis (POCA)

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. A similar practice is also done in Canada by Health Canada.

Medication Error Prevention and Analysis (Look-alike/Sound-alike Testing)

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.

This research process isn't mandatory for every pharmaceutical company, but utilizing a testing methodology as noted above are part of the Best Practices that many regulatory agencies like to see. It's common practice to get the asset's branding team comfortable with primary and backup names to have an insurance policy in the event of unforeseen regulatory challenges during the name review and approval process.

BRANDING YOUR ONCOLOGY ASSET

In naming oncology assets, trends have emerged that have shaped the brand names, that naming firms will deliver to clients. While three distinct trends standout in oncology, there is one commonality that connects these trends and is highly specific to branding oncology drugs.

Unlike any other therapeutic area, drug naming in oncology leverages and focuses the naming strategy around the mechanism of action. Cancer hits different pathways and receptors and by incorporating these into the brand names it makes it more intuitive for doctors to recognize the drugs and know which ones treat certain types of cancers. In the last five years this strategy has become highly sought after and nowadays, it is very rare to see companies not explore this type of brand naming strategy.

With this naming strategy widely practiced in oncology, brand names for cancer drugs more commonly represent one of three naming trends:

Names Derived from Scientific Attributes

Names Derived from Generic Name

Names Derived from Brand Aspirations

Once you have viable brand names that encompass your creative, scientific and commercial goals it's time to begin the path towards regulatory approval.

THE GLOBAL REGULATORY ENVIRONMENT: GETTING A BRAND NAME APPROVED

Similar to how we set up the overall pharmaceutical brand naming 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 between the agencies to sponsors and naming firms has improved. As rules and regulations change, the regulatory bodies are being much more transparent and becoming stewards for drug name 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 aforementioned regulatory agencies. 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 review 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 established collaboration with key members from the FDA, as noted in the published guidance.

Health Canada has made significant advancements with their guidance as a reflection of its complex health system and desire to streamline and raise awareness of its approval process. During the first half of 2014, Health Canada has published 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 adopt a clearly defined methodology for name submission. Where FDA and EMA encourage certain submission requests, Health Canada will require them.

The latest changes published by the EMA is the 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 went into effect January 1, 2015 and the full details can be found via the EMA's guideline.[2]

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 their brand names approved through the EMA before approaching the FDA.**
- **Or, companies may submit brand name review submissions concurrently to try to save time.**
- **The process to get the same name approved by the EMA and FDA could take considerably longer than it does now, with less names being reviewed.**
- **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 oncology assets 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 methodology based on industry knowledge to every branding naming process will help ensure global clearance and approval for a sponsor.

[2]"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 President, Andy Cuykendall. Their combined experience spans over 45 years and work with all of the top 50 big pharmaceutical companies. With projects ranging from brand name development and clinical trial branding, to non-proprietary naming 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 inVentivHealth.com/AddisonWhitney.

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inVentiv Health has supported 80% of all oncology drugs approved by the FDA over a five year period* with clinical development and commercialization services. This includes clinical development and launch support for novel therapies, including immunotherapy oncology drugs and immune checkpoint inhibitors. Our Clinical Division has extensive immunotherapy experience, conducting 23 studies on 15 compounds over the past five years and our Commercial Division has decades of experience launching and supporting oncology portfolios. Read more at inVentivHealth.com.

*2009-2013