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Naming of drug molecules and pharmaceutical brands

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ABSTRACT

For running any business or organization their products or services should be of utmost quality keeping other things aside. These products or services are known in commerce by their names. These names are called brand names and these are assigned by the owner or innovator or researcher or sponsor of that product or service depending on the type of produce and various parameters. Though company introduces the brand in commerce but after its (brand's) establishment, brand becomes the identity of company. Brand names are most important attribute of a product after its quality and packing from end user's (customer) point of view. Successful brand names never escape from the memory of consumer. Few such brand names are Bislery, Maggi, Vicks, Surf Excel, Coca-Cola, Google etc. Few reputed and well known pharmaceutical brands are Corex, Lipitor, Gleevac, Viagra etc. In present article various process to name a drug and a pharmaceutical formulations' name (brand name) have been described. Article throws light on generic, chemical and brand names of a drug or formulations besides few case studies and guidelines.

Keywords: Brand, generic, name, pharmaceutical, WHO, USAN

1. INTRODUCTION

A brand is a name, term, design symbol or any other stuff which is viewable and differentiates that stuff from other company's product or services. A brand is a trust imposed by its users in that product or service. This faith in the brand is accumulated over the years while using the same product again and again by the end user. A brand helps the consumers to identify and purchase a brand because of its quality and ability to satisfy the customers in a desired way. This basic principle also applies to pharmaceutical brands. In this case the customers are the patients who resort to medicines recommended by physicians. By registering a brand, the owner of the pharmaceutical brand protects the goodwill of the business. The registered owner of a pharmaceutical brand receives the right to use the registered brand. The owner can stop other traders from using his brand without his consent. The potential return on investment from choosing an appropriate brand name should compel any entrepreneur to devote time and effort to getting it right. A persuading and powerful brand name delivers immediate, direct benefits in terms of sales and consumer loyalty, as well as indirect competitive advantages when raising capital or offering shares of stock to the public. Another major reason for taking the necessary steps to select the best available trademark is to protect the owner's already sizable investment of time, money, and resources in developing the drug. Safety has become a major element in the naming of a new proprietary drug because consumer confusion over drug's brand names can have deadly consequences (Stephen C et al. 2000). A pharmaceutical brand is different from other brands in the sense that the former has a generic name too besides a name given by proprietor of that product. If the company launches a new drug molecule in market with a convincing, impressive and everlasting (doctor and patient friendly) name and sound then it will persists in the memory of not only customers (patients) but also healthy ones. The name should be recalled in no time. Once the brand is established as the leading one in its therapeutic segment then all the subsequent names falling in that category will probably live in the shadow of this original brand. Names worth mentioning here are Xerox, Bislery, Pepsi, Lux, Corex, Steptsils, Eno etc. Here quality is of paramount importance because if innovator products like Xerox, Maggi Bislery etc. Would not

have been effective and quality-filled then people would not have demanded even other brands with these brand names. In present paper, an attempt has been made to describe in details about generic and brand names of a drug and a formulation respectively. Various rationales and cases have been mentioned to make paper lucid and comprehensive.

Names of a drug

A marketed drug has three names: a chemical name, a generic name, and a brand name.

Chemical name: A chemical name is decided on the basis of chemical structure of drug and is used primarily by researchers. A drug's chemical name is long and usually difficult to pronounce and remember; consumers, physicians, and pharmacists are therefore better served by referring to the drug's generic name. The chemical name is generally not used in practice, unless it becomes the established or used name such as sodium chloride. Chemical names are not given in any of the standard manuals, such as the Physicians' Desk Reference, official books like United States Pharmacopeia (USP), or available software.

Generic name: Drug's official name is generic name throughout its lifetime world over regardless of who made it, how it was made, where it was devised. Generic name is commonly used by health care professionals and is usually created when a new drug is ready to be marketed. Although the manufacturer or sponsor of the drug has the exclusive right of manufacture during the 17 years of the drug's patent, it never owns the generic name. The manufacturer or sponsor of the drug usually initiates the request for a generic name, but the generic name is always in the public domain and there is no need of using such letters as TM or ® or © with generic names. Once the drug's patent expires, other manufacturers may make the drug, referring to it by its generic name. In the United States, the generic name must first be approved by the U.S. adopted name (USAN) council. The USAN council is responsible for creating and assigning a functional generic name to the drug. Before being approved by the council, the generic name must be screened to ensure that it does not look or sound too similar to any other generic or brand name and must also be considered appropriate for the specific drug. After approving the generic name, the council submits the name to WHO, which has final approval. The name is published in the trademark bulletin of the pharmaceutical research and manufacturers of America to allow comments or protests. If no such comments are objections are received then the name is considered final. After being approved by WHO, the drug is assigned an international nonproprietary name i. e. generic name. The USAN council adheres to a list of established guidelines in name selection. The most important criterion considered when issuing a generic name is the usefulness of that name to health care providers. The name should be short, easy to pronounce, and euphonic. The name cannot be misleading or confusing; prefixes implying a general descriptive adjective, such as new or improved, would not be accepted, nor would prefixes suggesting the manufacturer's name or an anatomical designation. A stem (a word common to members of a related group of drugs based on their use) is included so that shared characteristics (such as pharmacologic action) can be identified. For example, anti-inflammatory drugs commonly have an "fen" stem (ibuprofen, acetaminophen, diclofenac). The council uses many other specific guidelines; such guidelines include rules for preferred spelling, use of isolated letters and numbers and hyphenation, and rules for drugs that contain radioactive atoms. Federal law makes it compulsory to use generic names in advertising and on labels and brochures. The generic name is essential to pharmacists and other health care professionals, primarily because of the stem. Because of the USAN council's systematic approach to developing a generic name, pharmacists "can often tell you the chemical composition of it and what its indications and adverse reactions are. If a drug ends with "pril" they know it belongs to the class called ACE (angiotensin-converting enzyme) inhibitors.

Brand Name: Although the generic name is in the public domain, the brand name (the legal term for brand is trademark) is owned solely by the manufacturer and can be created as soon as the generic name has been approved. Unlike generic names, which are created by the manufacturer in conjunction with the USAN council, choice of the brand name is motivated by marketing considerations and solely rests with the innovator/organization of that molecule. Brand name is chosen by the company that wants to market the product and it is a marketing decision, however, the FDA must approve the name. Although the USAN council is actively involved in name selection, the FDA has authority over drug labeling and is essentially responsible for approving or disapproving the brand name of the drug. If the USAN council receives a submission for a name it considers inappropriate, the council will suggest another name; but if the FDA disapproves of the name, the manufacturer must propose a new brand name. The FDA tries to avoid excessive similarity between brand and generic names. Creating a generic name is a science and it does not influence the sell of that brand but creating a brand name is more of an art and it absolutely alters the selling of the brand. Here it should be noted that if quality product is not produced then brand names prove futile. USAN council has exact guidelines for assigning generic names, but the guidelines for assigning brand names outline what a company should not do while designing a brand name. As long as drug companies adhere to these guidelines, they are essentially free to choose any name for their products.

In october 1999, the FDA transferred the evaluation of proposed new drug names to the newly formed Office of Post-Marketing Drug Risk Assessment (OPDRA), which was part of the Center for Drug Evaluation and Research. At OPDRA, the intensity of the evaluation was augmented. The ultimate goal was the same; to avoid names prone to medication mistakes. In January 2002, the FDA, as part of a reorganization of its risk management function, created the Office of Drug Safety (ODS) and transferred

the responsibility for proprietary name reviews and analyzing medication errors data to a division within this new office named Medication Errors and Technical Support (METS). The proprietary name review begins when the owner of the new drug submits its proposed proprietary name(s) to the appropriate medical review division, which forwards it to METS for risk assessment. This may be as early as the end of Phase II of clinical development (testing of drug candidate in patients before launching in commerce). METS will evaluate no more than two names in its review. The names must be listed in order of preference and, if the first candidate is approved, no evaluation will be done for the second name. The standard of analysis is whether the proposed new drug name sounds or looks confusingly similar to another generic or branded drug. Drug names that sound alike can lead to errors in verbal medication orders and drug brands that look the same can be confused when written in prescriptions and dispensing orders. A safety evaluator in METS examines the overall safety risk of the new name. This name review includes a comparison of the new name against all existing proprietary and generic drug names marketed in the United States. The fact that the proposed new drug name may have been "allowed" by the Trademark Office or registered as a trademark is not considered in the evaluation process. ODS and its METS division are concerned only with the assessment of risk created by the drug name as used in a clinical context. The empirical testing part of the evaluation includes handwriting analysis in which test prescriptions and medication orders incorporating the proposed drug name are created and evaluated at both the hospital and pharmacy level. Verbal analysis is also conducted in simulated clinical environments to assess potential communication errors with other sound-alike drugs. The results of these studies are evaluated by a panel of ODS experts, and a written evaluation is forwarded to the Medical Review Division for that drug. A drug name that is tentatively approved must also undergo a second review 90 days prior to the approval of the drug itself. This second evaluation is limited to a comparison of any potentially confusing proprietary and generic drug names that have been approved after the initial evaluation of the new drug name. A crucial element in this dual regulatory approval process is timing. It does no good to obtain a FDA-approved drug name if another party owns a trademark registration for the same or similar mark that conveys the exclusive right to use the mark with a pharmaceutical product in the United States. On the other hand, a trademark registration for a pharmaceutical product is useless without FDA approval of that proprietary brand name. To avoid such a potential stand-off, pharmaceutical and life science companies must carefully consider the anticipated time table for clinical testing and FDA drug approval. It is always advisable to conduct trademark clearance searches of several alternative names for a new drug before selecting the name or names to be submitted to the FDA. Trademark applications for the final candidates should also be filed before the names are submitted to FDA to lock up trademark rights to the selected proprietary drug names. The trademark owner then has 3 years to establish use of the mark in commerce and obtain the registration. This gives the drug maker legal priority over the trademark drug name for 4 years or more while it pursues FDA approval of the drug and its proprietary brand name (Linda G et al. 1998).

What decides the brand names?

Pharmaceutical companies usually begin developing a brand name during Phase I of the IND (investigational new drug) process. There is no bible of rules for devising a brand name of any pharmaceutical products, which is also true for produces or services falling in other categories. The biggest criterion is brand name should not fall prey to controversies of any sort. Plus brand name should not reflect or mean any unacceptable stuff, at least in the countries where it has to be launched. Drug companies use several criteria in selecting a brand name. First and foremost, the name must be easy to remember. Ideally, it should be one physician will like, short and with a subliminal connotation of the drug. Gone are the days when the brand names were decided on gut feel or company's employees could submit their favorite name ideas to executives who would choose arbitrarily among them. Today there are well defined processes and ways to emerge with a brand name. A brand name may be a noun, an adjective or whatever. In the past 10 years, inventing names for drugs has become a big business. Today drug companies hire branding consultants two or three years before their drug hits the market to craft a powerful, unique name that will entice physicians and patients. It also takes expertise to create any original name. To develop a trade name, drug-makers often work with branding agencies that use massive databases to help them generate unique names. Marketing departments are often very influential. The cost of the consultation depends on the number of names to be evaluated and ranges from $100,000 to $700,000. There must be no trademark incompatibilities, and the company must take account of the drug's expected competition.

The names often make use of linguistic tricks, such as plosive letters (P, T or D) to convey power, or fricative letters (X, F, S or Z) to imply speed. This, in part, helps explain the number of Xs that show up in drug names. The marketing industry has been infatuated to letter X e.g. Nexium, Clarinex, Celebrex, Zinetac, Corex, Xanax, Zyban and Zithromax. These letters are popular because they look better in print, make sounds people like saying and are associated with innovation. Moreover this flamboyant and swashbuckling letter X is associated with science fiction, high tech, computers, and automobiles. As per James L. Dettore (president of the Brand Institute, a branding company based in Miami who has tested 8,400 drug names in the last seven years and successes include such brand names as Lipitor, Clarinex, Sarafem and Allegra) the letters X, Z, C and D are phonologic and these subliminally indicate that a drug is powerful. Few brand names even denote the gender of the brand. Most words ending with the 'a' sound suggest feminine gender. This is true even in the Indian context e.g. Diana, Prada etc. The research done by several experts show that the phonemes, vowels and consonants convey different

attributes. For example, the sound 'b' connotes slowness and also reliability. The consonants 'f', 'v','s' and 'z' connote speed. 'Z' is the fastest of them all. It's also considered the most powerful. No wonder, pharma brands Zedex, Zupar, Zoloft, Zofran, Zocor and Zyprexa are successful names. Before giving green signal to the name Levitra (another brand that contains drug sildenaphil; a competitor of Viagra), researchers tested not only doctors' reactions to various names, but also the potential that the name could be mistaken for another drug. In the market research sessions, interviewers asked doctors to write down the proposed brand name and the instructions for taking the drug, as if they were writing an actual prescription for a patient. Doctors' handwriting samples were analyzed, particularly the sloppy ones, to check for resemblances to other drug names. They looked at the names with various angles for varied reasons e.g. extra loops at the end and if the names resembled exiting brands or other generics. They also listened to how doctors with various regional accents pronounced or mispronounced the names, to see if any of them might be confused with other drugs during a telephone call to the pharmacy3. Additional guidelines call for names to be simple to pronounce (with only one way to say it and no more than four syllables). Generally brand names should not make advertising claims that may not be supported with fact. But there are brand names like Wellbutrin (an antidepressant), Revital (an immunomodulator), Celebrex (an anti-inflammatory agent), Claritin antiallergic formulation), Khansigul (for treatment of cough), Sardi Ja (to rid of cold). These brand names perhaps have something to do with their intended uses, indicating a growing trend in the use of experimental names for various formulations (Gauri c, john W et al. 2007).

Stories behind some pharmaceutical blockbuster molecules

Currently the world's largest selling drug molecule, atorvastatin, is sold under the brand name Lipitor (owned by Pfizer). It is a lipid regulator. Lipitor derived the name from "tor" of atorvastatin (the generic name with the stem statin) and "or" to sound a cardiovascular system. Names Infliximab, bevacizumab, rituximab, alemtuzumab and cetuximab are anti cancer drugs. These denote the technology behind that drug" monoclonal antibody (suffix mab in all these names). The well-selected name Viagra comes from prefix "vi" connoting vigor and vitality, while the tail portion comes from Niagara, conjuring images of the power and fury of Niagara Falls. In this way perhaps the perfect name for a drug medically recommended for an erectile dysfunction. Levitra, the Viagra competitor, comes from elevate and Le indicates masculinity in French, and vitra can refer to vitality. In India, version of Viagra is called Silagra, from its generic name, sildenafill.

The original name proposed for Rogaine (a hair growth promoter formulation) was Regain (perhaps indicating regaining of hair), but the FDA did not permit as it promises too much.

An interesting case is of blockbuster anticancer drug Taxol. It is a natural product isolated from the bark of Pacific Yew plant (Taxus brevifolia). It was isolated by at Research Triangle Institute (RTI), USA. As it is common the individual who discovers a new natural product, also names it. The researcher thus called this new chemical Taxol (tax from taxus, ol as in alcohol). He used the name in his 1971 publication announcing the chemical structure. After that, chemists working with the compound used this name; partly because it's very complex structure virtually precluded the systematic chemical name. Probably because it was so hard to obtain it in quantity, the compound lay unused on a shelf at national cancer institute (NCI), USA. until the late 1980s. Interest was kindled again when Susan Howrwitz discovered that the drug acted by a previously unknown mechanism. The late Matt Suffness at NCI then made a concerted effort to pursue the compound. As part of this, NCI apparently requested proposals from the private players to join in developing taxol as an antitumor drug. The proposal tendered by Bristol Myers was deemed to be superior to the others leading to the company being awarded the agreement. Somewhere along the line, however, someone either forgot to register the name taxol with the USAN as the non-proprietary (generic) name for that substance or may simply have been unaware of this requirement. This kept the door open for Bristol Meyers to acquire Taxol as a trade name allegedly via the purchase of the Trademark of an old laxative product and to have the non-proprietary name paclitaxel accepted as the generic term of Taxol. This meant that chemists would no longer be allowed to talk of taxol generically but would have to refer to paclitaxel, unless they were talking about BM's drug in which case that would be Taxol (Donald G et. al. 2009. Anita c et al.2009). The Drug Discovery and Development webpage of RTI reads "Among our substantial achievements are the discoveries of the life-saving anti-cancer compounds Taxol® and camptothecin as well as other major products for a variety of clients". It means even the institute which shown world first time Taxol can not use this name without the superscript because the brand is owned by Bristol Meyers as they own the name. Had it been protected by the RTI then this exciting name would have been the sole property of RTI as generic name and not the brand name.

DISCUSSION AND CONCLUSION

Pharmaceutical trade names are made-up words coined to convey a sense of power or speed or tranquility without promising a cure. A brand name is a composition of individual sounds called phonemes, which represent attributes. If these attributes are desired by consumers, they would want to try it instantly (especially OTC products viz Vicks, Itch Guard, Crocin, Iodex to name a few). Companies want a brand name to be appealing (which may fetch them billions of dollars). The FDA doesn't want implied medical claims through brand names. As more and more pharmaceutical products are developed and brought to market, the task of naming a new drug becomes both more difficult and more important. Studies estimate that anywhere from 7,000 to 20,000 people die or are

injured each year in the United States because of drug name confusion. A well-chosen name for the new proprietary drug is essential to maximize customer goodwill and brand loyalty and can be a tremendous asset in building public awareness and market power during the exclusive selling period granted to a patented drug product. Conversely, a failure to develop and protect memorable, strong trademarks for pharmaceutical products can adversely affect the value of a company to prospective investors. There are thousands of drugs and brand names on the market, and a mix-up can occur at any level of the distribution chain: the prescribing physician, the pharmacist filling the prescription, the hospital staff administrating the medication, or the patient consuming it. Bad handwriting and miscommunication can defeat even the most precautionary dispensing procedures. In summary, drug companies seeking to establish protectable brand names for their products must successfully overcome two significant regulatory hurdles. The first is the registration of the drug name as a trademark with the United States Patent and Trademark Office. The second required regulatory review process is the approval of the proprietary drug name by the Food and Drug Administration (FDA) as part of its approval of the new drug itself. While both the FDA and the trademark office's review processes attempt to assess a likelihood of confusion, the Trademark Office's primary focus is to ensure that consumers are able to distinguish and identify the source of the drug product bearing the trademark. Its review and approval of the proposed trademark, which, if successful, culminates in the registration of the mark, does not involve an evaluation of public safety. The FDA's focus is to prevent errors in prescription, dispensing, and consumption that might result from confusing and misleading drug names and drug labels. The Trademark Office's approval process may be seen as a means to prevent confusion over product origin, while the FDA's review seeks to avoid brand name confusion that may lead to medication errors. Some facts about nomenclature of drugs prevailing in USA:

- Generic drug names do not begin with the letters H, J, K or W because these letters do not exist in some of the 130 countries that use U.S. generic names, or have different sounds in various languages.
- The USAN council has imposed a moratorium on the use of the letters X and Z as the first letters in generic drug names because they often sound alike at the start of words.
- The USAN council avoids prefixes and stems like brev, vel mal or mor because they imply other things (brevity, velocity, bad or death, respectively).
- Approximately 60 percent of the world's generic drug names come from the U.S. drug industry.
- The FDA rejects about one-third of all proposed trade names.
- More than 300% Increase in Global Pharma Trademark Filings: Between 1980 and 2010, the number of pharmaceutical trademarks filed increased by more than 300%. A total of 238,010 pharmaceutical trademarks were filed globally in 2010. China Filing Most Pharmaceutical Trademarks in 2010: Chinese firms filed 36,105 pharmaceutical trademarks in 2010, more than any other region globally. China was followed by the US (27,545) and India (26,123). Some surprise emerging markets such as Vietnam, Venezuela and Turkey were also among the top 10 countries filing the most drug trademarks in 2010[8].

(All the brand names cited here are owned by respective organizations and they are cited here fully from view point of publication and not to favor or defame any brand/company or to influence the public/patients'/physicians' choice. Original views of experts are greatly acknowledged).

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