

dosage form preference

OTC PRODUCTS: UNDERSTANDING
CONSUMER EXPECTATIONS AND
PERCEPTIONS

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How over-the-counter (OTC) products are perceived plays a role in their success or failure. This article looks at the patient as a consumer who evaluates products based on dosage form and its presentation.

Pharmaceutical drug product development focuses mainly on the therapeutic effect of new molecular entities by measuring the impact on the clinical parameter and biomarkers of a disease. With increasing availability and choices in drug therapy, the requirements for overall therapeutic outcome and pharmaco-economic evaluation have gained importance in drug development. The recent quality guidelines of the ICH have also drawn considerable attention to the patient by stating that, "In all cases, the product should be designed to meet patients' needs and the intended product performance" [1].

Understanding patients

Therefore, in order to meet patients' needs, it is important to understand the different patient populations and the patients' capabilities, perceptions, and behaviors within their disease, as well as their therapeutic schedule. Over the past few years, the needs of the pediatric patient population have gained attention due to guidelines intended to foster consideration of this patient group when developing new products and/or extending product lines [1, 2].

A recent article also provided evidence that the geriatric patient population—the fastest growing patient population and a major consumer of medicines—is poorly understood and seldom considered during drug product design and development [3]. Those oversights can diminish treatment success. According to Haynes et al., accounting for patient needs in drug product design

as a means to increase patient adherence and compliance has a “far greater impact on the health of the population than any improvement in specific medical treatment” [4].

Physicians know that patients participate instinctively in their drug therapy based on their capabilities, knowledge, attitude, belief, perception, experience, expectation, and wishes [5]. Today’s patients are less willing to accept a drug therapy without a detailed explanation from the physician, because they seek and make use of drug information that’s widely and easily available on the internet. Today’s patients also take responsibility for their own health and treatment, much more so than in the past.

The OTC environment

Retail sales of OTC products (excluding Walmart sales) reached \$16.8 billion in 2008, according to the Consumer Healthcare Products Association (CHPA) [6]. A survey conducted by the National Council on Patient Information and Education (NCPPIE) showed that the most commonly used OTC drugs were analgesics, cough and cold medicines, anti-allergic preparations, heartburn and indigestion relievers, products for treating constipation and diarrhea, wound care, and dermatologic treatments [7]. While pharmacists are often consulted, many patients choose their own OTC products based on their preferences and perceptions. A study performed by the

University of Huddersfield suggests that “visual aesthetics” is as important to consumer decision-making today as the traditional elements of price and functionality [8].

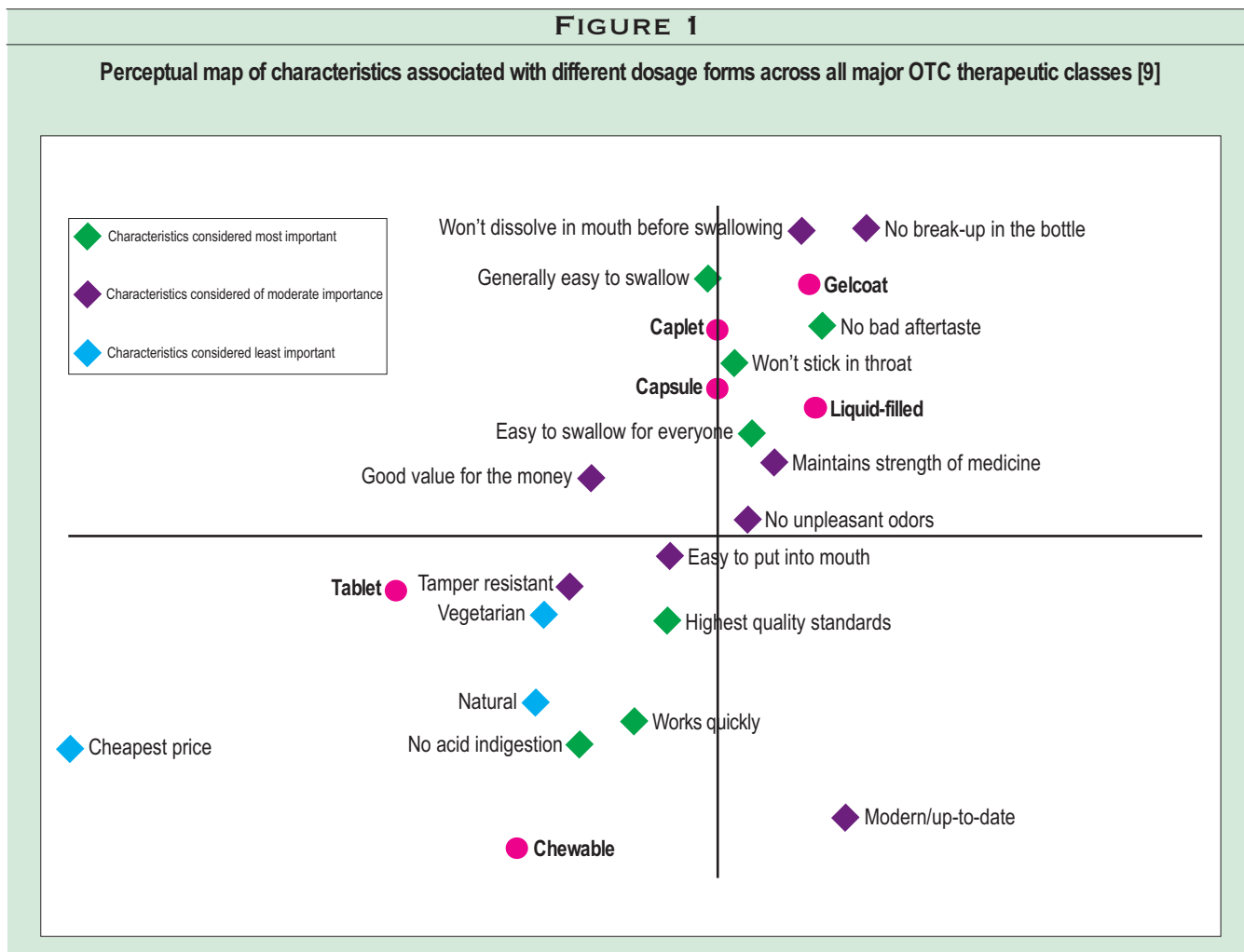
Dosage form expectation and perception

To investigate the consumer perceptions of different dosage forms and designs, Guidelines (formerly Advanced Analytics) built a perceptual map based on 1,650 responses during one-on-one interviews with 754 consumers in 2002 [9]. See Figure 1. The consumers were asked about their usage of specific dosage forms and their attitudes about the forms, as well as their preferences and their interest in other dosage forms [10]. To standardize the nomenclature of the responses, a board displaying various tablets, capsules, caplets, gelcoats, liquid-filled, and chewables was provided.

One major finding, as Figure 1 indicates, is that the characteristics important to consumers—“easy to swallow,” “won’t stick in the throat,” “no bad aftertaste,” and “maintains strength of medicine”—are closely associated with capsules, caplets, gelcoats, and liquid-filled. Tablets and chewables were most associated with “tamper resistant,” “vegetarian,” and “cheapest in price.” Interestingly, consumers also placed importance on the characteristics of “won’t dissolve in mouth before swallowing” and “no break-up in the bottle” when making their decision.

FIGURE 1

Perceptual map of characteristics associated with different dosage forms across all major OTC therapeutic classes [9]

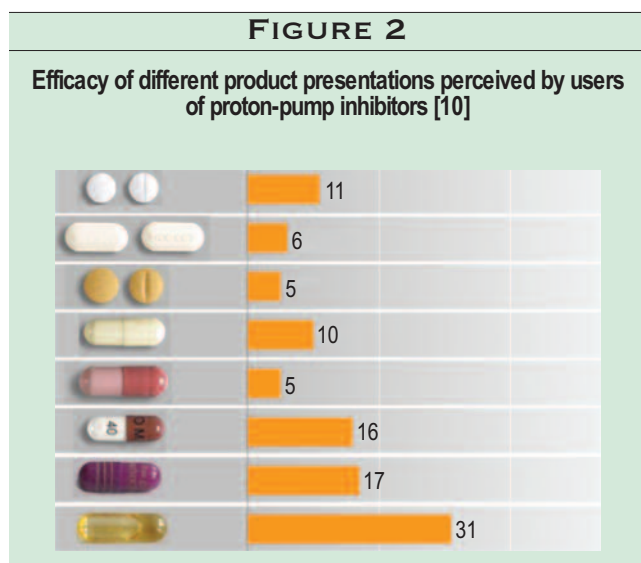


Those characteristics were most associated with caplets and gelcoats, as well as traditional capsules and liquid-filled.

A similar study was performed in Europe by GfK, which investigated the ideas consumers associate with oral formulations, such as tablets or capsules. The study population comprised users of proton-pump inhibitors [11]. In the study, 100 users were asked in face-to-face interviews what they expected from a drug product and how they perceived different drug product presentations with regard to efficacy, tolerability, rapid effect, high quality, easy intake, differentiation, modernity, and brand identity. To provide a reference for judgment, samples of four different capsule presentations, three different tablet products, and one liquid-filled capsule were offered to users.

The most important expectations cited by users were fast action, ease and convenience of intake and swallowing, absence of side effects, and brand recognition. The study identified colors as the most recognizable attributes of the drug products with regard to brand recognition. Colored and imprinted capsules, for example, were found to be more memorable than a white capsule. The branded capsules (colored and imprinted) and the liquid-filled stood out with regard to efficacy, rapid effect, quality, differentiation, modernity, and branding.

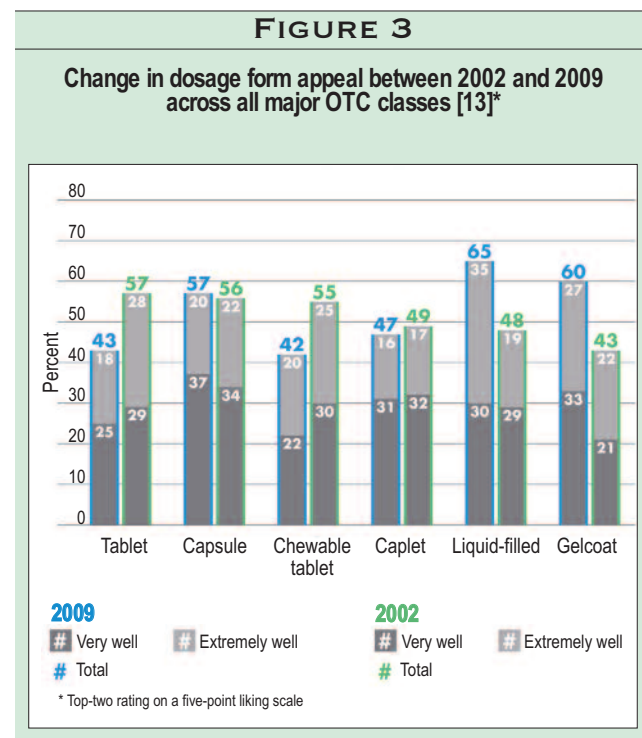
In terms of swallowing ease, users preferred the branded capsules and the small white tablets. The study also revealed that liquid-filled are seen as a superior to tablets and traditional capsules. Liquid-filled, as shown in Figure 2, were specifically associated with efficacy because of the visible liquid. These studies demonstrate some of the expectations and perceptions consumers use when they select their medications. They also show that consumers use their experiences to evaluate the different dosage forms.



While traditional dosage forms have existed for many years, today's OTC companies often take a more consumer-centered approach in innovating dosage form and presentation. These presentations allow manufacturers to differentiate their products based on the expectations and preferences of non-prescription drug users.

Consumer perception surveys conducted in different European countries clearly showed that, in regard to dosage form, tablets remain the most widely used because of their history. They are the "learned dosage form" in some therapeutic areas. However, the same studies confirm that the European popularity of tablets faces challenges from modern, more attractive forms. Capsules with innovative designs pose a major challenge to tablets [12].

The introduction of these new choices and consumers' history with them prompted Guidelines to repeat its study in 2008/2009 [13]. The new study included several liquid-filled and rapid-release gelcoat products. Introduced in the 7-year interval between studies, these new forms allowed investigators to measure changes in consumer usage and preferences. And change they did, as Figure 3 shows. Consumer preference for tablets and chewable tablets—ranked first in 2002—declined significantly, while preference for liquid-filled and gelcoats increased to rank at the top in consumer preference in 2009. Because capsules remained strongly preferred in consumer perception, it appears that the shift towards liquid-filled and rapid-release gelcoats came mainly from people who had been consumers of tablets and chewables.



Conclusion

Non-prescription drug products (OTCs) are widely used to treat most common symptomatic ailments. And because consumers purchase the products directly, it's the consumers who make the purchase decision, usually independently. But the drug product itself, along with its dosage form and presentation, influence that decision. Consumers also inform themselves about OTCs from a variety of sources, including pharmacists, colleagues, family members, the internet, and advertising. At the point of purchase, however, the final decision is based on the

expectations and perceptions associated with a specific OTC drug product. And that's where the studies show that consumers value certain forms because they offer a positive experience: ease of swallowing, won't dissolve in the mouth, and no bad aftertaste, as well as the drug product's perceived efficacy and the absence of side effects.

For the majority of consumers, brand recognition is also an important aspect in their selection process because it connotes high quality. As reviewed by Stegemann, colors are a guiding principle for humans and can be considered an important feature of drug product design and branding [14]. Moreover, with the increasing number of multiple medications used, especially within the geriatric population, colors can increase drug safety by providing visual differentiation and clear identification.

Consumers respond to more convenient and innovative dosage forms, especially if the forms are perceived to connect with an important attribute. The appeal of liquid-filled and gelcoats has gained in the past few years and replaced tablets and chewables as the preferred dosage forms. Also, since capsules of vegetarian origin resonate with many consumers' lifestyles, they may begin appearing in products beyond the traditional herbal supplements [15]. The capsule remains one of the most preferred dosage forms, especially when colors and imprints are used in branding [16]. One example is the "purple pill," a term that became synonymous with Nexium, which is a capsule formulation.

Understanding consumer expectations and perceptions is a critical aspect in the concept, design, and development of new generations of consumer products. Dosage format has to be integrated at an early stage of product design, because the delivery method can fuel product innovation. As the segment expands, companies will have to seek new formulations and product presentations that address the needs of future OTC customers.

T&C

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