Strategic use of oral drug delivery systems in the lifecycle management of consumer healthcare products

Whether you need to contemporize a well-known but mature brand franchise, expand on an upcoming or recent Rx-to-OTC switch, or broaden the audience appeal of any OTC or VMS product, the strategic use of novel drug delivery systems can provide opportunities to grow a brand and increase sales.

According to the National Institutes of Health, drug delivery systems are “engineered technologies for the targeted delivery and/or controlled-release of therapeu-

Building brand equity and driving organic growth continues to be a challenge for marketers of oral consumer healthcare products, including both over-the-counter (OTC) drug products and vitamin, mineral, and dietary supplement (VMS) products. This article reviews the benefits of novel oral drug delivery systems to product performance and user satisfaction and provides examples of brands that have successfully incorporated new drug delivery systems into their product lines.
tic agents” [1]. Drug delivery systems can take many forms, such as oral solids, oral liquids, topical, nasal, transdermal, drug/device combinations, and more. This article will focus on oral delivery, including both immediate- and controlled-release tablets, capsules, and softgels; orally disintegrating tablets (ODTs) and thin films (ODFs); and confectioneries. The advantages of these oral forms can include accurate dosing, portability, ease of use, and extended shelf life.

**US consumer healthcare market**

Consumer healthcare products represent a large and growing business. According to the Nicholas Hall 2019 DB6 database [2], global sales of OTC and VMS products in 2018 were $135.4 billion, up 4 percent versus the prior year. The US is the largest market, representing nearly 25 percent ($33.6 billion) of all worldwide sales in 2018. This was a 3 percent increase versus the prior year.

In the US, key therapy areas in the consumer healthcare market include cough/cold/allergy products (21 percent), analgesics (12 percent), gastrointestinal (11 percent), VMS products (36 percent), dermatologicals (12 percent), and lifestyle OTCs (9 percent), as shown in Figure 1 [2]. Other than for dermatologicals, the vast majority of brands use oral delivery forms, especially tablets, capsules, ODTs, and confectioneries.

Each of the top 10 US OTC brands for 2018 exceeded $300 million in sales, as shown in Table 1 [2]. With the exception of Flonase (GlaxoSmithKline), which uses nasal delivery, each of these top 10 brands uses oral delivery forms for many individual products.

**Using drug delivery in lifecycle management**

To effectively use drug delivery in lifecycle management, you must understand consumer needs, know the delivery technology alternatives, and implement a sound development and manufacturing process. Developing a checklist of all the critical steps, with expected outcomes and due dates, will give you a clear plan to execute.

**Understanding consumer needs**

Understanding a brand’s existing and prospective consumers can provide great value when assessing appropriate delivery forms. For existing products, is current business declining, flat, or growing? Determine the profile of the brand’s current users, especially heavy users, depending upon the type of product.

Companies often use traditional qualitative and quantitative market research to measure how individuals will react to new delivery systems and how the delivery system can impact brand purchases. Be sure to include the cost investment when analyzing whether a new delivery system can improve a product or formulation and its ultimate effect on the business model.

**Selecting the right delivery technology**

The objective of expanding a brand via drug delivery is often to appeal to a broader user group with a better and bigger range of choices. In the long run, this has the additional benefit of increased patient or consumer compliance, especially for brands that require daily use (such as vitamins and fiber supplements). For any given brand, the optimal use of drug delivery can involve a variety of improvements over time to help achieve increased compliance. The most common improvements include forms that make the product longer-acting, faster-acting, more palatable, or more consumer friendly.

**Longer-acting products.** In the early days of self-selection therapies, oral tablets often had fast-release properties, which provided immediate therapeutic benefits (typically 4 to 6 hours) but required more frequent dosing. Over time, manufacturers developed longer-acting or sustained-relief therapies with existing compounds, effectively delivering medicament over a longer time period (up to 12 hours).

The switch to OTC of formerly Rx therapies expanded on the long-acting therapy model. For example, Aleve was first offered as a 12-hour OTC pain reliever in the mid...
1990s, and 12- and 24-hour forms of the low/non-sedating antihistamines Claritin, Zyrtec, and Allegra came to the OTC market in the early 2000s. Prilosec OTC is another Rx-to-OTC switch that offers 24-hour therapy.

**Faster-acting products.** Fast-acting products are becoming more important, especially for remedial products. For example, pain medicines that get into the system quicker for potentially faster relief are expanding. A good example is Advil Film-Coated tablets, which, according to the Advil website “goes to work in minutes” and “dissolves quickly and absorbs fast to stop pain before it gets worse” [3].

**More palatable products.** The accelerated use of chewable gummies as a dose delivery format in the VMS space in the past 15 years has helped to expand the category and related brand franchises. For example, Nature Made, the number one brand in the US market [2], has a broad presence in the dietary supplement market. The brand offers traditional tablets as well as gummies in a variety of forms, therapies, and sizes. While the gummies are likely targeted to bring in new consumers, the brand continues to offer tablets, which appeal to its traditional user base.

**More consumer-friendly products.** Consumer friendliness relates to factors such as convenience, portability, and swallowability. For example, ODTs provide easier consumer dosing than traditional tablets, in many cases without requiring water. Portable forms such as thin films, lozenges, chewables, and mints, also provide an easy way to dose for consumers with “on-the-go” lifestyles.

**Implementing a sound development and manufacturing process**

To increase the likelihood of success, it’s critical to assemble the right team of both internal and external professionals, secure buy-in upfront, and ensure sound fiscal management.

**Internal versus external development.** Determine whether the company has the capability, capacity, time, and financial resources to develop a product with a new drug delivery system or whether the company should seek an external partner. If the company has the internal capability and owns or has access to intellectual property, developing the product internally will provide the most control and generally result in cost efficiencies, but it’s a good idea to evaluate external options.

Scouting activities at trade shows is a must, and being aware of what’s available may not only be important for a company’s own products, but may also provide a better understanding of what other companies are evaluating for their products. A broad review is good at the outset; then you can narrow and prioritize options once you understand what may appeal to your target user base, what is novel, and how quickly you can get the product to market.

**First to market with novel solutions.** The use of drug delivery supported by intellectual property protection is particularly important to justify consumer healthcare company investment, both in development activities as
The future of drug delivery

Projecting forward, oral consumer healthcare drug delivery growth will likely include easier-to-swallow tablets, better-tasting chewable and confectionery forms, and faster- and longer-acting forms. R&D efforts that can facilitate measurable therapy may be new goals that can be achieved with combinations of novel drug ingredients and new delivery systems. Finally, unit doses to ensure proper therapy will likely become greater factors for consumer health brands.

It will also be important to examine ongoing technology development and innovation in prescription medications as consumer healthcare companies focus on the future and building their brands. Smart technologies and custom-designed therapies, such as breakable pills and profile doses may impact the future development and use of OTC products.

Maintaining a consistent strategy will be key, and securing novel rather than “me too” solutions will be critical. Companies must carefully validate new technologies with consumer research and support them with awareness-building strategies. Developing or finding truly novel technologies will clearly be a challenge for innovation and new product efforts in the consumer healthcare space.

Avenues to help identify and secure novel technologies include delivery-specific conferences and seminars, targeted trade journals, university searches, patent screening, evaluating innovation in other related and unrelated industries, retail store checks, understanding ex-US innovation and brands, and internet searches. In-house innovation sessions with broad participation by professionals from a variety of disciplines can be a great way to find that next breakthrough technology. Marketers might identify the right external drug delivery “specialist” or “scout” to help support their growth initiatives. The market will be competitive, but there will be many opportunities to succeed.

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Case studies

Mucinex. Mucinex was launched by the Adams Respiratory Products organization and has been marketed by Reckitt Benckiser since 2009. Considered by many to be the OTC success story of the millennium, Mucinex was an estimated $10 million generic prescription medication before switching to OTC in 2002. It has since become a top 3 OTC powerhouse, with 2018 US sales in excess of $660 million [2]. The brand used strong marketing efforts targeting both consumers and doctors and promoting a novel delivery mechanism (sustained-release tablets).

The brand has expanded to build its retail presence and appeal to consumers and healthcare professionals, and now includes formulations for chest congestion, cold & flu, sinus, cough, and children, and is available in a variety of forms, including tablets, liquid gels, powders, and liquids. The brand even offers combination forms for daytime and nighttime relief [5]. Each new formulation and dosage form has helped to grow the brand’s position as a market leader and expanded its footprint to a different type of consumer.

One-A-Day and Flintstones vitamins. The One-A-Day vitamin brand dates back to the 1940s, when it was first introduced as an oral tablet multiple vitamin to be administered on a daily basis. In the ensuing years, Miles, and later Bayer, expanded the One-A-Day brand footprint in order to appeal to a broader market. In 1968, Bayer licensed the Flintstones trademark and successfully established the Flintstones brand as a children’s vitamin product sold at retail to consumers [7].

Over time, the Flintstones brand also expanded, and in 2005, the company began marketing an easy-to-take confectionery form—chewable gummies—which had broad appeal to its market. Within a few years, the One-A-Day brand began marketing a gummy form (One-A-Day VitaCraves), offering a “fun” way for adult consumers to take vitamins daily. The form helped transform the One-A-Day brand and increase its appeal. Over time, Bayer has expanded this business to a variety of sub-segment user groups (including women, men, and teens) and has introduced additional products with broader indications (such as immunity support, energy, and heart health with omega 3). Bayer has also used the gummy format for its Phillips Colon Health probiotics.
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The author thanks Nicholas Hall & Company for providing US OTC industry and brand sales data. For further information on the company, please visit nicholashall.com.