Since the invention of the pressurised metered-dose inhaler (MDI) approximately 60 years ago, the industry has undergone constant evolution. If we think back over the events and global changes in just the past 30 years, it becomes clear how difficult it is to forecast what lies ahead. Thirty years ago, in the mid-1980s, compact discs were just being introduced and the Cold War was an ongoing concern. As we know, the pharmaceutical and drug delivery markets were very different then too, a testament to the furious pace of change in the past several decades. The industry has undergone an evolution on many basic levels, with players adapting to compete, be first to market, cope with changes in raw materials and formulations, and meet new regulations. As environmental concerns rose, The Montreal Protocol led to the phase-out of chlorofluorocarbons (CFCs), which changed the inhalation industry dramatically.

Today, we see the evidence of that successful adaptation. Both MDIs and dry-powder inhalers (DPIs) combine to form a market valued at US$37 billion (£23 billion) annually. Of the 920 million devices sold each year, MDIs represent about 60% of the volume and 40% of the sales value. MDIs are primarily used to treat chronic obstructive pulmonary disease (COPD) and asthma, although they can be used to also treat a wide range of other therapeutic areas. In fact, we are now seeing a resurgence of nasal MDIs for allergies.

While the MDI market moves forward, patient compliance is growing in focus, highlighting one likely trend for the future. An estimated $290 billion in additional costs is spent annually due to non-compliance, and estimates show the industry loses approximately $188 billion in profits due to this issue. These “human factors” have become more of a concern for the US FDA, which is leading to greater regulations around the issue.

Beyond the increasing focus on compliance, financial pressures have also acted on the industry. A growing number of mergers and acquisitions has significantly consolidated the industry players and resulted in moves to and from outsourcing, and back again. Blockbusters have lost

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In this insightful overview piece, Richard Beesley, Inhalation Drug Delivery Business Manager at 3M Drug Delivery Systems, discusses how the pharma industry has changed over the years and how these changes impact today’s industry (in particular the pulmonary and nasal delivery device industry). Richard also examines how current global factors from both within and outside the pharma industry, such as increasing patient awareness and the current regulatory focus on compliance and human factors, can affect business. In addition, he addresses how recent innovations from 3M, including the 3M™ Integrated Dose by Dose Counter and the 3M™ Nasal MDI, can be used to meet the needs of today’s market.

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DRIVING INNOVATION IN A CHANGING WORLD

As veterans of this business know, there is no “typical” lifecycle for an inhalation product. A seemingly robust product’s lifespan can be quickly reduced by new developments or generic competition. If we consider how drugs are developed, we see that the first step—the research phase for chemical targets to address particular therapeutic areas—can take anywhere from one to three years, and sometimes more. Once this phase is complete, the process moves on to development, when the drug goes through testing to determine its safety, efficacy, and a range of other attributes in order to prepare it for regulatory submission and approval. This phase can add seven to 10 more years to the timeline. Finally, the product is ready to hit the market. At this point, companies can expect 6-10 years of patent protection before generics are introduced. The product can then stay on the market—albeit in a more competitive environment—for any period of time.

It is at this stage that differentiation becomes key for a product’s success, protecting it from generic competition. To achieve this, pharmaceutical companies and their partners must devote significant time and resources to research and development. 3M Drug Delivery Systems has seen this strategy pay off successfully with the introduction of dose counters. The 3M™ Integrated Dose by Dose Counter was developed to help improve compliance and to give patients a reliable and easy-to-use tool that builds their confidence in their MDI (see Figure 1). The dose counter has a displacement-driven design that eliminates under-counting, while the split-count principle avoids over-counting. With a familiar look and clear display, it requires no additional training for patients, and its ergonomic design suits a wide range of users.

This technology was developed specifically with patients in mind, with significant research devoted to understanding the features that are most important to users of the device. Testing has shown that the dose counter not only meets patients’ expectations, but actually enhances their experience of using an MDI. This technology is the first integrated dose counter with FDA approval available to third parties.

DIFFERENTIATING TO MEET PATIENTS’ NEEDS

An innovation like the dose counter can be a big help to a company looking to differentiate its product in the marketplace and drive patient preference (Figure 2). Today’s patients are increasingly looking for simpler ways to administer medication to fit with their busy schedules. We need look no further than the growing number of smartphone apps and other tools patients use to monitor their health intelligently in order to see that they expect, and want, to be more informed about their treatments. Given this trend, it is not surprising that patients state that they value having an accurate dose counter on their inhalation device, and that it ranks as one of their favourite features.
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As noted previously, there is a strong drive in the pharmaceutical industry towards taking human factors into account to promote patient compliance. To do this, a business must not only consider the therapeutic needs of patients, but also the needs they develop from using other products in their day-to-day lives. For example, the mobile telecommunication industry is in a constant competition to enhance device interfaces – a competition driven by increased awareness and consideration of how customers interact with products. The world of drug delivery is no different, and the same level of innovation is needed. At 3M, patients are surveyed on every aspect of an inhalation device at the prototype level to help developers ensure that new technologies will be patient-approved and patient-preferred. Nearly any change to a 3M device is directed or strongly influenced by patient feedback.

Of course, any innovation that gains attention and preference from patients will likely eventually be mimicked by competitors. This fact is not unique to the pharma industry. In reality, companies simply must invest in new research and development on an ongoing basis; it’s the cost of doing business today.

At 3M, this is evidenced by a new nasal MDI device, which is driving real change in the nasal inhalation market. Again, the development of this product was strongly driven by research into patients’ wants and needs. Data showed that patients found aqueous pump sprays for allergic rhinitis to be unpleasant in both sensation and taste, as well as unhygienic. The new 3M™ Nasal MDI, however, is designed with a no-drip spray design to eliminate nasal run-off and post-nasal drip, and to minimise aftertaste. It also has a twist-and-lock design that is simple, compact and patient-approved. A technology such as this can make an ideal route for pharmaceutical companies seeking a rapid extension of their inhaled corticosteroid into allergic rhinitis, or for those seeking a device edge for new nasal treatments.

COPING WITH REGULATION

Even when a pharmaceutical company is doing everything it can to drive innovation and proactively manage product lifecycles, there are still many challenges from outside forces to keep in mind. The tighter regulatory requirements of the US are becoming more common around the world, as emerging markets use US and EU regulations as their benchmarks. This trend not only increases the standards, but ultimately the cost to enter these markets.

Furthermore, legislation surrounding good manufacturing practices (GMP) for pharmaceutical companies has been put in place in many countries, which enhances the final quality of the product. It also improves working conditions within pharma and drug delivery manufacturing, a welcome development. Many companies in the industry already have high internal standards in place. For instance, 3M utilises Lean Six Sigma manufacturing and process controls to ensure the quality of products. Increasing legislation in this area helps ensure that everyone considers these factors.

Regulations also come into play as more blockbuster patents have come close to expiry or expired. In these cases, regulators must determine how to manage and control new generic copies of these products. Currently, bio-equivalency of the generic copy is the focus of regulations, which is driving technologies that can replicate existing products while navigating the extremely complex patent landscape. Testing of these products centres on comparing the new generic with the innovator in order to confirm that it fits within the existing approved product specification. All of these regulatory developments work as a constant driver of change as companies attempt to stay ahead of both legislation and the competition.

THE IMPACT OF THE OUTSIDE WORLD

Material substitution is also presenting distinct challenges. Even a seemingly simple material substitution can have a major impact on a product. The pharma industry uses many materials in a low volume compared with other industries, so it can sometimes be significantly impacted by changes driven from the outside. For example, we use polymers in sealing rings, and these same polymers are used in high volumes in other industries. If another industry requires a design change or switches to an alternative product, the pharmaceutical community can be impacted. The cost of the polymer can increase dramatically, or we may even have to re-qualify the new variation of polymer to ensure it still complies with regulations. In some cases, both of these changes can occur, with the manufacturer being impacted by both increased cost and re-qualification. Considering the broad range of components that the inhalation industry uses across the 920 million devices produced each year, combined with heavy regulatory requirements, the situation is a recipe for continual change.

Given these constant changes, many companies in the pharmaceutical industry look to outsource or in-source at various stages in the value chain. For instance, a company may buy late-stage drug developments that it can then commercialise directly or with a partner. By doing this, the company can scale-back its upfront investment. Additionally, the practice of outsourcing commercial manufacturing of products is growing. While companies initially were outsourcing to emerging markets in order to reduce costs, today we are seeing more use of specialist contract manufacturing organisations in the EU and US. By working with these manufacturers, a pharmaceutical company can gain added value in the total lifecycle of its product.

FINDING THE RIGHT PARTNER

Any investment or partnering model must of course be aligned with a larger strategic intent, but outsourcing of manufacturing is often attractive to companies which do not want to make the capital investment in equipment and infrastructure that is required to manufacture inhaled products. However, in order to optimise a product’s chances of success and extend its lifecycle, it is vital to pick the right partner—one that has stability, experience, and the advanced knowledge required truly to add value.

With more than 30 years of global MDI manufacturing experience, 3M Drug Delivery Systems has worked with many pharmaceutical companies to help differentiate their products and position them for a long life. With a proven track record of innovation and swift adaptation to new challenges, 3M has provided its problem-solving expertise and forward-thinking skills to numerous partners. With recent innovations like the 3M Integrated Dose by Dose Counter and the 3M Nasal MDI, 3M has demonstrated its unmatched capabilities in responding to patients’ needs, regulatory demands, and the constant drive for product differentiation.

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3M DRUG DELIVERY SYSTEMS
INHALATION DEVICES

There are many reasons to choose 3M as your MDI partner. This is the one that counts.

3M’s innovative dose counter and nasal inhalation systems provide a differentiating delivery method, giving our partners a competitive edge.

Through the development of intuitive patient-friendly innovations, 3M’s MDI devices and components enable your treatments to stay on the cutting edge while making life better for patients. We offer:

- Leading edge devices ideal for aerosol delivery through the lungs or nasal cavity, for Asthma, COPD and Allergic Rhinitis.
- Technologies that meet growing market demand for patient-friendly devices such as nasal MDIs and dose counters.
- Products designed and developed with patients in mind, ensuring product differentiation, and resulting in a competitive advantage for our partners.

With a 50 year history of innovation and success in inhalation technology, 3M’s MDI experts can help you gain a competitive advantage.

Make life better for patients today at www.3M.com/pMDI